

To: Kent Woods, CEO MHRA
Copy: June Raine, VRMM
Copy: Ian Hudson, Licensing

10 December 2010

Regarding Janssen-Cilag's application to get Concerta approved for adults in Europe

Janssen-Cilag (Johnson & Johnson) is now applying for adult indication (ADHD) for Concerta in Europe (attached). The MHRA is handling the application.

The application should be **disapproved**, mainly for the following reasons:

The company has not adhered to and fulfilled the conditions for continued marketing authorisation of Concerta, as advised by the EMA and decided by the European Commission 27 May 2009. [1]

The MHRA must be aware of the fact that Janssen-Cilag and the other manufacturers of methylphenidate products **have done nothing effective** to handle the safety issues decided by the European Commission. It can be supposed that the MHRA, EMA and the Commission were sincere when stating that the actions listed in the decision were **conditions to be adhered to and fulfilled**; meaning that if the listed actions were *not done* the marketing authorisation for Concerta would be withdrawn.

We are now at the point where Concerta and other methylphenidate products should be withdrawn from the market in Europe – and very far away from a situation where Concerta could be approved also for adults.

IN ANNEX IV (P. 65) TO THE DECISION FROM THE COMMISSION, CONDITIONS OF THE MARKETING AUTHORISATION [1], from 27 May 2009, we find the following points:

- **“Long Term Use effects**
The MAHs [Marketing Authorisation Holders] committed to provide a detailed feasibility assessment for a scientifically valid, well designed and suitably powered long-term safety study to examine specific endpoints for the following outcomes:
adverse cognitive outcomes
adverse psychiatric outcomes (e.g. mood disorders, hostility and psychotic disorders)...”

On this point Janssen-Cilag has (together with the other manufacturers of methylphenidate, called “the Consortium”) tried to obstruct the needed follow-up

actions about the psychiatric harmful effects of methylphenidate. The so called Feasibility Assessment submitted by the companies is only an aggressive effort to get away from the much needed safety studies. The EMA has been asked by the European Commission to give an answer to what has been done by the Agency by reason of the now infamous report from “the Consortium”; a report saying that the companies do not intend to (“can not”) do any follow-up studies in the area of psychiatric harmful effects. [2] See a full analysis of the report from “the Consortium” in the letter ***A request for decisive actions from the European Commission to initiate required safety actions about methylphenidate products*** from 5 March 2010. [3] [http://jannel.se/letter Consortium ADHD.pdf](http://jannel.se/letter_Consortium_ADHD.pdf)

The MHRA has written to the MAHs objecting to the obstructions from the Consortium to do the needed safety follow-up. I quote from a letter sent by MHRA to the Consortium (released as part of a FOI-request in September 2010 (FOI 10 413):

“The market authorisation holders (MAHs) have provided a very detailed assessment of the feasibility of conducting a scientifically valid, well-designed and suitably powered long-term safety study of the effects of methylphenidate on cognition and psychiatric outcomes as requested by CHMP resulting from the Article 31 referral. Their assessment concludes that such a study is not feasible, mainly due to reasons of severity of ADHD (i.e. potential for confounding by indication), difficulties with selection of a suitable comparator group and obtaining a suitable sample size.

We consider this to be an overly negative conclusion and contend that such a study is achievable. It is recognised that randomisation in the context of a clinical trial or an observational setting, is not possible, but it is still possible to design a prospective cohort study that would lead to interpretable data. Incorporating the element of propensity score adjustment to address the confounding by indication problem, and a multivariate analysis of data contrasting exposed and unexposed ADHD subjects could still lead to meaningful conclusions.

Although the MAHs point to the difficulty of ensuring in the long term that the unexposed patients are truly unexposed, it is still possible to explore from a range of sources suitable groups that would render the multivariate adjustment for confounding factors between exposed and unexposed groups entirely feasible. The MAHs have been unduly pessimistic in their projection of 60% drop out in their sample size calculations and we would suggest 25% to 30% is more likely.

Subject to the outcome measures examined, and the assumptions regarding drop outs, odds ratios in the region of 1.5 noted in the MAHs’ table are feasible to examine against a background of 20% in the unexposed group.”

The MHRA’s overall conclusion and recommendation to the MAHs for methylphenidate products authorised in the EU on this issue was as follows: “The MAH assessment of the feasibility of conducting a long-term safety study concludes that such a study is not feasible, mainly due to reasons of severity of ADHD (i.e. potential for confounding by indication), difficulties with selection of a suitable comparator group and obtaining a suitable sample size. We consider this to be an overly negative conclusion and contend that such a study is achievable. The MAH should propose how a suitable study could be performed, taking into consideration the comments in this report on how many of the suggested limitations could be overcome.”

I can guarantee that the Consortium has continued with its obstructions, giving more and more arguments why this study cannot and should not be done.

I expect that the MHRA now has *ordered* the Consortium to DO the required study and that the Agency will not tolerate any more delays in this. I look forward to see a copy of that directive.

- **”Growth, Development and Sexual Maturation**

MTA Study. *“Effects of stimulant medication on growth in the MTA (Multimodal Treatment Study of ADHD)”* follow-up, carried out by the MTA Cooperative Group. The MAHs will evaluate the final report of the study, when published, and will update the RMP [Risk Management Plan], and where appropriate the SPC/PL [Summary of Products Characteristics/Product Label], to reflect the findings.”

In actual fact the relevant evidence for decrease in growth rates is already there: Methylphenidate **does** decrease growth rates. The relation has already been proven in the MTA study, the results after 3 years cannot be ignored (even if the manufacturers and strong drug proponents with financial conflicts of interest do their best to ignore and disprove the relation). In the MTA 3 years-follow-up we find the conclusion that the drug treated children “...show stimulant-related decreases in growth rates after initiation of treatment, which appeared to reach asymptotes within 3 years without evidence of growth rebound”. [4]

“Study on sexual maturation: a 2-year, long-term, open-label, prospective investigator initiated study in the US on 150 adolescents (12-17 years) with ADHD, to determine whether treatment with methylphenidate will prevent smoking in this population.”

As for the follow-up about sexual maturation, no data have reached the Swedish Medical Agency, and it can assumed that this follow-up will take the same route as the ordered studies and follow-up in the area of Prozac for children – meaning a scandal where nothing of value is done in the end. [5]

- **“Cardiovascular and Cerebrovascular effects”**

It is reported that no data have reached the Swedish Medical Agency about the studies listed on this point. But instead very important data about the cardiovascular effects of methylphenidate have been revealed in the government funded long-term Raine study from Western Australia. [6] The following finding in the Australian government report should be added as proof to the already known serious adverse effects in this area: “The results also indicated that between the age of 8 and 14 years there may be an effect of stimulant medication on diastolic blood pressure above and beyond the well-established immediate short-term effects on cardiovascular function. The finding that consistent use of medication was associated with an average elevation 10mmHg at 14-years of age indicates that the long-term cardiovascular implications of stimulant medication-use need to take a high priority when determining directions for future research.”

- **“Drug utilisation studies, including evaluation of Off-Label Use/ Abuse**

The MAHs commit to provide all available retrospective data on an annual review basis for the next five years in all Member States where methylphenidate is used, to allow an evaluation of changes in usage over time. Where possible, measures of usage including variables such as information on total amount used, patient age, gender, indication dose,

duration of use, treatment continuity, comorbidities, concomitant medications, data on patterns of use, physician specialty will be used. This commitment will be reviewed after 5 years. In the Member States that are covered by the IMS database, the MAHs will also evaluate off-label use of methylphenidate.”

This condition for continued marketing authorisation is stemming from the alarming data described in Annex II of the Commission decision:

“The significant risks of off-label use, misuse and diversion were identified from the submitted data.”

“The significant risks” **are** already identified. If effective actions were taken by Janssen-Cilag and other manufacturers to fulfil this condition there would be significant risks that the full scope of the disastrous scene would be shown. Hence nothing effective is done in the area.

It has been very easy to prove that Janssen-Cilag has done nothing effective to fulfil this condition for continued marketing authorisation. **In actual fact all the requested long-term data (5 years) could already have been collected and analysed.** Instead the company (and other manufacturers) have **not even started** to use the very good resources available for executing this commitment.

The point of off-label use, misuse, abuse and diversion are of course crucial as regards the application for using Concerta for adults in Europe – meaning that the non-execution of the required actions on this point – and the data that have emerged – is enough for disapproving the application from Janssen-Cilag.

The fact is that Janssen-Cilag has not only not done anything effective on this point, but the company has also submitted false and misleading data to the medical authorities in Europe.

The data are as follow:

This is what should be done according to the Commission decision: “Where possible, measures of usage including variables such as information on total amount used, patient age, gender, indication dose, duration of use, treatment continuity, comorbidities, concomitant medications, data on patterns of use, physician specialty will be used.” Also data about off-label use, misuse and diversion should be collected.

And the resources in Sweden give all opportunities to fulfil this requirement via the Swedish Prescribed Drug Register [7] and other important Swedish registers (like the Patient Register).

As said in Annex IV in the Commission decision: “National Competent Authorities, coordinated by the Reference Member State where applicable, shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders” (followed by the list of conditions). However the National Board of Health and Welfare in Sweden has not heard about this obligation (the Director General says the Board has not been instructed by the Government to do anything in this area) and the Medical Products Agency says it has good intentions but cannot show evidence for having done anything. Janssen-Cilag has not been instructed by these national authorities to use

the very good registers and has not sought the cooperation with these authorities in fulfilling the requirement.

If used the Swedish Prescribed Drug Register could tell the FULL story about “total amount [of methylphenidate] used, patient age, gender, ... dose, duration of use, treatment continuity, ... concomitant medications, data on patterns of use” since July 2005, meaning that data for 5 years could be presented NOW.

Anyone looking for information about *diversion and abuse* of prescribed methylphenidate in Sweden will easily find an abundance of data. Via this link it is possible to read **103 pages** (from Swedish web sites) where the Swedish “users” tell about diversion and abuse of Concerta and Ritalin. The stories are in Swedish <http://jannel.se/concrit.Apr2010.pdf> [8], **excerpts are presented in English in Appendix 1 below.**

The stories about diversion and abuse tell about a scene already out of control. Full use of the Swedish Prescribed Drug Register for the years 2005-2010 would present data verifying the stories from the “users”.

Instead of providing “all available retrospective data” in this area, using for example the registers in Sweden, **Janssen-Cilag (Johnson & Johnson) is presenting wildly misleading data to the medical authorities in Europe** in its Risk Management Plan (RMP) from 23 November 2009. [9]

Misuse and abuse of Concerta is described in the RMP (p. 128-129) under the heading *Drug Abuse and Drug Dependence*. It is stated:

“CONCERTA has a unique pharmaceutical design that prohibits the dosage form from being crushed, opened, or emptied **making it virtually impossible to abuse it through injection, snorting, or inhalation means**. In addition, it is a long-acting prolonged-release product and **high, spiking blood levels that individuals may perceive as euphoric effects cannot be achieved with an intact dosage form**. Due to these characteristics the CONCERTA formulation would probably not be the preferred choice for methylphenidate abuse.” (Emphasis added.)

...

“The limited number of paediatric reports in the postmarketing database supports that CONCERTA treatment confers a low risk of drug dependence. **The formulation makes it difficult, if not impossible to effectively abuse; therefore, is not expected to have an impact with respect to overall public health.**” (Emphasis added.)

On page 127 in RMP it is said that the total number of postmarketing reports about drug abuse events for Concerta *worldwide* is 16 (!).

In the RMP it is stated (p. 123) under the heading *Important Potential Risk: Diversion*:

“**Diversion** is understood as the entry of illicit pharmaceutical products onto the unregulated market through a number of channels, eg, thefts of product from the legitimate supply chain, or **product obtained legitimately and subsequently diverted through various means** such as Internet sales.” (Emphasis added.)

...

“A total of 3 adverse events with preferred terms of Drug diversion have been received in the postmarketing database cumulative 01 August 2000 to 10 August 2009 (BRM Report, PSUR 2009). The limited information does not allow conclusions to be made regarding this important potential risk.” (Emphasis added.)

Three (!) reports *worldwide* since year 2000?

Some data about diversion of methylphenidate in the US are however presented in the RMP, but for Europe only the following is said (p. 124):

“From a review of public information sources, it appears that there are currently no databases in place at the EU or national Member State level to directly monitor pharmaceutical product diversion in the EU.”

All in all Janssen-Cilag (Johnson & Johnson) has not at all used the good Swedish registers to investigate strange prescription patterns (indicating diversion and abuse), and is presenting NO data at all about the abuse and diversion of Concerta in Europe. To make it even worse it is said that Concerta is **“difficult, if not impossible to effectively abuse”** and that it is **“virtually impossible to abuse it through injection, snorting, or inhalation means”**. The data from the “users” tell another story (see Appendix 1).

It must be taken for granted that the EMA does not accept the presented misleading data in the RMP.

In the RMP it is further stated (p. 118) under the heading *Potential for off label-use*:

“According to IMS covering CONCERTA retail prescriptions in the 4 major European countries where CONCERTA is available (Germany, France, Spain, and United Kingdom), from January 2003 to June 2009, **the vast majority (94.0%) of retail prescriptions of CONCERTA were prescribed to children and adolescents between the ages of 6 and 20 years.**” (Emphasis added.)

This is the **only** information about off-label prescriptions to adults in this 319 pages long document written by a company with immense resources to investigate and present the facts about prescriptions. If they instead of presenting these misleading data would present the facts from Sweden the following would be the text: **13 948 adults (19-) got methylphenidate (mainly Concerta, Ritalin) in Sweden 2009, while 17 331 children got the same drug. Meaning that 45 % of the prescriptions for methylphenidate were for off-label use, for adults.**

While Janssen-Cilag (Johnson & Johnson) presents data indicating that 94% of the prescriptions of methylphenidate 2003-2009 (in four countries) were for children – meaning this is not a problem at all, it is easy to present data showing that 45 % of the prescriptions for methylphenidate in Sweden 2009 were for adults.

Of course this is not a secret for the national authorities concerned. The question is only how it can be accepted that Janssen-Cilag (Johnson & Johnson) gives misleading, outdated information, as the data about off-label prescriptions to adults.

Data from the Swedish Medical Products Agency (for 2009) indicate that **for around 1000 cases (!) Concerta, Ritalin and Strattera (the approved ADHD drugs) had no or vanishing effects and/or harmful effects**, and that the prescribing psychiatrists, as the next step in the experimentation, wanted to get a license for dexamphetamine (Metamina). The applications (mainly for adults) give an abundance of evidence about the patterns of use and that the doses of methylphenidate had to be **increased** after a while to uphold the drug effect. They show that the prescribing psychiatrists in many cases **had to move up to even stronger drugs** (dexamphetamine) when it was no longer possible to increase the dose of methylphenidate. All these cases should have been reported to the Adverse Events Registry, but very few of them were. (In fact only 16 reports of adverse events for Concerta were reported to the Adverse Events Registry for 2009, while we for the same time could see *hundreds of such reports for Concerta in the license applications for dexamphetamine.*)

Some examples of the adverse effects reported in connection with the applications for dexamphetamine licenses were:

“...very powerful, almost physical anguish”; “severe anxiety”; “joint pain, uncommunicativeness and suicidal thoughts”; a lot of side effects; increased anxiety, even panic attacks; depression and increasing anxiety; “sudden emotional swings from high happiness to sadness and tears”; “headache, increased anxiety and memory disorders”; “sensitive, insecure, paranoid feelings implied in the higher dose”; “a lot of side effects”; “patient even at a couple of occasions had been confined to bed”; “increased aggression”; “severe side effects such as nausea, vomiting, weight loss, anxiety and depression”; “severe side effects”; “had to be discontinued at a relatively low level due to anxiety attacks”; “very difficult adverse side effects”; “developed a psychosis which led to care in our intensive care department”; “Increased debilitating anxiety”; “adverse events in form of deep depression with apathy”; “intolerable side-effects”; “got anxiety and reinforcement of aggressive feelings”; “sharp and unexpected side effects with all treatments (ranging from allergies to hallucinations)”; “severe side effects were noted”; “got psychotic experiences...Two serious suicide attempt last month”; “severe side effects such as irritability, depression of mood state”; “very strong side effects”; “more speeded up, aggressive”.

See Appendix II for a long list of examples.

It must be very clear that Janssen-Cilag (Johnson & Johnson) is not adhering to and fulfilling the conditions for continued marketing authorisation decided by the Commission. The company must be informed that the marketing authorisation for Concerta is about to be withdrawn.

It must also be very clear that the application for approval of Concerta for adults must be disapproved.

Janne Larsson
Reporter

(Snöbollsgård 22
129 45 Hägersten, Sweden)
janne.olv.larsson@telia.com

References:

- [1] The European Commission, Decision and Appendixes about methylphenidate products, from 27 May 2009; Decision and Appendixes: http://jannel.se/anx_55708_en.pdf
- [2] “The Consortium”, *Feasibility Assessment of a Study of Long-term Effects of Methylphenidate on Cognition and Psychiatric Outcomes*, 30 October 2009, http://jannel.se/Consortium_ADHD-drugs.pdf
- [3] Larsson, *A request for decisive actions from the European Commission to initiate required safety actions about methylphenidate products*, 5 March 2010, http://jannel.se/letter_Consortium_ADHD.pdf

- [4] MTA Cooperative Group (2007), Effects of Stimulant Medication on Growth Rates Across 3 Years in the MTA Follow-up, *Journal of the American Academy of Child & Adolescent Psychiatry*, Volume 46(8), August 2007, pp 1015-1027
- [5] MHRA, Assessment Report, *Post-licensing commitment to assess sexual maturation in children (Prozac)*, 9 September 2009. <http://jannel.se/MHRA.Assessment%20Report.2009.pdf>
- [6] Raine ADHD Study: *Long-term outcomes associated with stimulant medication in the treatment of ADHD in children*, February 2010, http://www.health.wa.gov.au/publications/documents/MICADHD_Raine_ADHD_Study_report_022010.pdf
- [7] Wettermark et al, The new Swedish Prescribed Drug Register—Opportunities for pharmacoepidemiological research and experience from the first six months, *Pharmacoepidemiology And Drug Safety* 2007; 16:726–735, <http://www3.interscience.wiley.com/journal/112749905/abstract?CRETRY=1&SRETRY=0>
- [8] Data from Swedish discussion forums, 2007-2010. <http://jannel.se/concrit.Apr2010.pdf>
- [9] Johnson & Johnson, Risk Management Plan Concerta, 23 November 2009, <http://jannel.se/RMP-ConcertaNov2009.pdf>

APPENDIX 1

Swedish user reports about Concerta and Ritalin

On getting high/getting a buzz on the doses doctors prescribe:

- "I think Concerta 36 was excellent to chew ... feel somewhat high on 2";
- "Ritalin 40mg is not so strong, you need 2 such to experience a fairly drunk [state], like Concerta 54mg is much better ...";
- "... Has Ritalin prescribed for my possible ADD and take a total of 40mg in the morning for it ... I am very easily influenced by the Ritalin, I feel very alert and I am almost in a euphoric state the next few hours after I took it. I can sit in trance ...";
- "54-100 mg do I need if I should be high on it";
- "2 40mg now. Damn it is actually power in these. Thought in the beginning that there would be some shit, but they may be called "good enough";
- "Have a friend who becomes truly stoned at 20mg (and yes, he has taken much drugs too), myself, who need about 40-60";
- "From my own experience you can be stoned if you chew a few 10 mg";
- "Takes concerta 18 mg to concentrate pretty good, I take 18mg 2, then I am just speeded as a parrot".
- "I absolutely become high on Concerta ... 60-100 mg will be good enough";
- "took 3x36 MG [Concerta] and got a fucking buzz";
- "yes one can get speeded on a 36mg's Concerta, but more is desirable ";
- "I am using concerta 54 mg daily. Well, I can get high on it sometimes. Could be badly speeded";
- "I have at least one friend who I have seen to become very speeded on 1 ½ tablet 36mg Concerta ...";
- "Buy Ritalin myself and it's only 10mg, but I'll be right nice on them! but the high will not be for very long ";
- "Is it just 18mg [Concerta] you have to eat 4-6x to get a buzz that works..";
- "You can become sick high by Methylphenidate, I become "socially high" on a 37mg-tab ."
- "What is a normal dose of ADHD drug (beginners and experienced)?"
- [Answer:] "Something between 40-60mg I would say, more is needed after an hour or so to keep the buzz alive ..."
- "ritalin 40 mg are not so strong you need 2 to experience a pretty good buzz, think Concerta 54mg is much better ...The buzz: SPEED, generally happy, want to talk about feelings..."

"...euphoric effects cannot be achieved with an intact dosage form".
Johnson & Johnson, RMP, 23 November 2009

"54-100 mg do I need to get stoned on. works very well...almost like taking amphetamine but a bit worse because it is shorter and doesn't give such an intensive high...."

"You don't fucking need 100 tablets, it was 40mg's capsules. People felt eating 2-3. Then if you injected Ritalin you didn't even need 40mg, and it was a damn strong shot. So do not talk about stuff you do not have a clue about."

"I'm no expert on Concerta, but I've taken 90 mg at the most ... On it, and even on a little smaller doses, I got a high that clearly has been in the same class as amphetamine (enormous energy, outward direction, commitment, euphoria..."

"My God .. That's because amphetamines are the drug of choice, in order to feel harmony and euphoria. It is not because you have ADHD that you feel comfortable on amphetamines .. That's because it is a drug that makes you feel like you want to feel. People seem to have incorrect expectations of amphetamine that you should be "nervous" and "running around" - and that it is "unique" that you become concentrated and creative on amphetamine .. Haha. It's a classic effect."

"From my own experience you can get stoned on nibbling a few 10mg [Ritalin]! The capsules I have never been prescribed so have not actually tested them .."

"Another thing I noticed is that with Concerta [54 mg] about 20 minutes after I took the pill, I get an extremely pleasant "buzz" feeling. A sort of euphoria. It does not last as long, 1 hour maybe, but it's so fucking beautiful in that first hour! I will be happy, social, energetic, feel good simply! Is that how it feels with "normal" amphetamines too, or?"

"I can chew two pieces of 36mg and feel a little speeded. but it always ends with anxiety and shit, hate Concerta."

"I have eaten Ritalin 30mg for 3 days and has not had the desired effect yet, but feel more merry about 2 hours after eating a tablet. Then go over to where I get my heart rate sky-high and trembling all day and finally a "withdrawal" consisting of nervous twitches and I get tired. Do hope that it will improve over time ...(Diagnosed with ADD and autism, faint traces of Asperger's.)"

On increasing the dose to get a better buzz:

"I have strong ADHD and Ritalin, 80 mg per day, have never taken it as I should, just abused but if I crush and snort 40mg I get a little power, and I continue then I get greatly speeded ";

"I do not know what Concerta costs on the black market because I have been diagnosed with ADD and get the shit basically free ... This is my speed, can catch balls and count faster than a calculator at doses of 108mg or more ";

"I have concerta prescribed fr 72mg (2 * 36mg daily, to get "high" I take at least 10 54mg chewing of course because it is prolonged";

"I started taking a bit more than I should because I did not know the impact I had at the beginning, and it became just more and more each time. Now I sit here, a monthly ration finished in 3 days";

"Have just managed to get my psychiatrist to prescribe Ritalin to me (rimmed up that I have ADHD etc.), But...capsules tablets of 10 mg. My question to you experts is how many of those should be taken to have a bit fun? ";

"Take Concerta (same as Ritalin) right now, have it prescribed. 1.begins within ten minutes, going up in 30 minutes to. Important: crushed orally if you eat something extra to, a fruit or banana maybe. The increase is VERY nice, I must say, especially if you listen to music. ";

"but I am prescribed 3x 54mg Concerta ... since 2 months back but sometimes it takes 4-5 (not crushed) so you feel good for many hours ";

"I've had both Concerta and Ritalin prescription since some week even though I have a long addiction behind me with cs. This my psychiatrist knows about. I made the ADHD test and had clear ADHD. The worst thing is that I can not help but chew the capsules in concerta to get a kick effect.. ";

"I ate 8 pieces Concerta 36 mg total, shared and swallowed them last Thursday. Was super sick speeded so I would not even touch one of those pills again ha ha .. it was super sick. Felt so bad on withdrawal 10 times worse than on the ordinary amphetamine cannot even describe the low and tormented myself night until morning without being

"The formulation makes it difficult, if not impossible to effectively abuse; therefore, is not expected to have an impact with respect to overall public health."

Johnson & Johnson, RMP, 23 November 2009

able to sleep more than maybe 10 minutes all night and just stare at the ceiling and felt bad .. am still not normal after those .. but you know well but never feel normal anyway I really do prefer real amphetamine!"

"yes it is good to have more than two 54mg, but be prepared for a tough withdrawal. Everyone do not get an annoying withdrawal but can imagine that most people get it. I think it is far worse than usual withdrawal from amphetamine."

"Of course to get a good buzz so I need to take 2 and a half Concerta 54mg"

"162 mg of Concerta is sufficient enough to get decently speeded!"

"I have a neuropsychiatric disorder (ADHD) and treated with Ritalin tablets 10 mg orally (active substance: methylphenidate). The dose I really need is about 2 times less than what I have been prescribed per month (managed to fool my doctor that I need more). The rest I have some fun with after I solve the tablets, filters, etc. so I can shoot it. When I shoot, I am almost always home."

On experimenting with different ways to take the amphetamine preparations to get a better buzz (chew, crush, snort, inject):

"Ritalin is so fucking nice, I love them. Smash balls or snort alternative mix with water the drink kicks in like hell between 20-80mg is usually enough for me one evening ";

"Ritalin is taken up in an excellent way orally and gives effect almost immediately. Ritalin is possible to shoot, and it provides a similarity to cocaine ";

"yes, Ritalin gives a buzz. similar to amphetamine I would say. I am using my medication nasally when I am partying, works fine. but can imagine to crush it and bomb it works very fine ";

"Concerta ... Add tab between 2 spoons, then take a hammer and hit so you get them apart, is also possible to inject this, but sticky, so best to swallow!";

"You can take it both orally and nasally, of course, different dosing then".

"Use to be on 40mg tabs [Ritalin] that I crush and take the best way!"

"If it should turn, I usually take between four and eight 36es [Concerta] .. If you do not want to chew them so it's a simple thing to take a knife and split them lengthwise ... However the withdrawal is not play with .."

"I took 80mg and felt a little speeded. Snorted 40mg and felt at least 4-5 times more speeded."

"It is possible to be stoned and the easiest is to nibble. Personally, I have to take at least 100 mg. [Ritalin] to be speeded, but *the more, the merrier.*"

"I tested my sister's Concerta a few months ago, I think I began with 4*36mg crushed. I got a nice feeling in the body that reminded a bit of tramadol, but less euphoria (though I do not have much to compare with)"

"Agree Concerta works great shit to snort. Do snort half 54 mg and take the other half orally (crushed) then I feel damn good for 2-3 hours."

"I have Concerta prescribed, most people think it is a pretty fun thing, but withdrawal is bloody boring, and sometimes even more annoying than on true A[mphetamine]. By the way I peel them and usually run at 2-3, it makes me a little bit happy..."

"Sitting at the moment and a bit fuzzy on Concerta I came across. Took 3 pieces, because I'm pretty inexperienced. Crunching them btw, tasted shit. Anyway, I got me a decent kick None überurus [big buzz] exactly but will do."

"Enough to snort about 50mg [Concerta] for me, and then I get totally comfortable "speeded"."

"Well, I know a guy who shoots Ritalin instead of amphetamine and now he also said that he thinks it beats better for him than what amphetamines do."

"I've always got a really nice buzz from them, and one can only hope that the effect would be there longer. The short half-life similar to that of coffee makes you have to snort in more every two hours to keep the high. The high, however, is very nice. A completely clean feeling of energy and focus."

"...it is virtually impossible to abuse it through injection, snorting, or inhalation means."

**Johnson & Johnson, RMP,
23 November 2009**

"Concerta is of course true nice to take. Nice buzz, talkative, speeded, emotional (but not so good if you have too many secrets)
The first time I took 2, 36R, crunching them. Felt gold, but was not prepared for withdrawal, so of course it sucked hard. Now I have to take around 100-120mg to get the desired effect."
"have eaten 5 peeled today and this is a horrible withdrawal."

On selling or giving away the preparations to others and in that way spreading the abuse:

"Ritalin ...mates with ADD do not take and I'll get them. 2 cans of 30mg 30 buttons in each ie 60 tablets. What are they worth? ";
"A buddy've fixed up some maps Ritalin that he thought to "feast" on. Is it easy to mix with alcohol, how cautious should you be? ";
"My buddies poked in the 3 tab of these ADHD medication when he was really drunk because of alchohol. Resulting in that he could [not] breathe, type slobbered all the time, impossible to contact every now and then and lost his breath when he was trying to sleep ";
"My friend (who...has DAMP) does not like to take his medication, and usually give it to me I do not have huge experience of drugs, just think that it can be fun sometimes. So, if I want to get the maximum effect of Concerta, how should I proceed? ";
"hey, one buddy has ADHD and is eating Concerta, so I wonder. How many 18mg tablets we need chew / swallow to get us drunk? ";
"I did try ADHD pills from a friend, Concerta, and yes, I started taking type - 4 pieces, chewed and swallowed, then I took some booze and beer";
"Have a buddy who had ADHD before. And he kept a jar with Concerta. But not so strong, he says (?). 30 tablets of 200 SEK. Good price? ";
"A friend has Concerta 18 mg and now, I wonder how the hell I'm going to abuse them (the capsules) like an instruction manual step by step".
"Remember when I took 300mg of my then girlfriend's Ritalin. There we can we talk about the worst I have experienced in form of withdrawal! Maximum anxiety and quite impossible to sleep even though I was exhausted, succeeded to go to sleep after 18 hours."
"The girlfriend has ADHD and Concerta 36mg has been prescribed. have tried a few times, even earlier today. There is nothing like pulling a rope in my opinion. Concerta lasts longer. With alcohol, it is actually quite nice. 'll have a great pleasure in the body, with a little shudder very often. Then I chewed the tablet before...Do not get speeded, or something like that, but calmer, and release of some concern. However, I have only taken 38mg at most."

**"A total of 3 adverse events with...Drug diversion have been received in the postmarketing database cumulative 01 August 2000 to 10 August 2009."
Johnson & Johnson, RMP,
23 November 2009**

APPENDIX 2

Some examples of the effects of Ritalin and Concerta reported to the Medical Products Agency in Sweden in connection with the application for dexamphetamine license:

- "Methylphenidate with small to moderate effect ... The treatment can also cause the patient stuck in the activities, as he tends to focus on very narrow areas ..."
- "Concerta 36 mg side effects...."
- "central stimulants ... been depressed, apathetic ... These symptoms disappeared when central stimulants was discontinued ... "
- "Concerta and Strattera, but patient had adverse reactions to this."
- "Tried to Methylphenidate but had severe adverse reactions with rash, swollen lymph glands in the armpits, altered vision, which recurred at each experimental treatment (tested a friend's Concerta earlier this summer) ..."
- "Methylphenidate ... of insufficient effect ... feels side effects such as palpitations."
- "Concerta patient ... just experienced anxiety and had high doses ..."
- "Ritalina Tablets ... significant side effects such as palpitations, restlessness, hypomania, falling asleep with very poor appetite. "
- "Strattera, Concerta...but without achieving a good effect and without being able to tolerate the preparations."
- "Concerta, but was discontinued when the patient became dizzy, had thoughts of harming himself and outbreaks..."
- "Ritalin dose of 45 mg. The effect has been insufficient, also troublesome side effects, sleep disturbance, shaky feeling, unsteady feeling, headache, dry throat, hyperhidrosis, tachycardia, palpation..."
- "Concerta, Ritalin, Strattera and Zyban have not yielded any positive effect ..."
- "Concerta, Ritalin...she becomes very lethargic on this medication ..."
- "Ritalina but then became depressed and had obsessive thoughts, the medication is discontinued."
- "The patient on a maximum of 126 mg Concerta and 20 mg Ritalin, without satisfactory results."
- "Ritalin SR resulted in poor sleep, poor appetite, and the boy became a 'zombie'."
- " ... tried treatment with Ritalin and then showed a paradoxical reaction with exacerbation of hyperactivity, impulsivity. "
- "Concerta prescribed, titrated to 72 mg in the morning. Not experienced relief of symptoms, rather...side effects such as headache. "
- "... ... Concerta, however, got more... speeded and depressed."
- "Strattera, Ritalin and Medikinet with inadequate effect...troublesome side-effects."
- "... The patient responded with depressive symptoms on methylphenidate."
- "... Concerta side effects such as stomach pain the Ritalin same side effects."
- "Ritalin ... allergic reaction with severe body itching"
- "... Concerta made him anxious and nervous, insomnia and nausea."
- "... methylphenidate had large, negative effects on appetite and weight."
- "Concerta ... troublesome side effects of anxiety."
- "... Tried Concerta, and Metamina Ritalin, many side effects and with very limited effect."
- "Concerta and Ritalin, but this did not work well."
- "... Ritalin was discontinued due to adverse events."
- "... Concerta, Ritalin and Strattera, but with side effects or insufficient efficacy."
- "Ritalin 30mg, 2 x 1, but unfortunately, altered mood with increased oppositional syndrome and aggression."
- "Concerta 54 mg / d for long periods without significant effect. The next try with short-acting Ritalin was also without significant effect. "
- "... Previously tried Ritalina, but then became depressed and introverted."
- "The patient has tried Concerta...resulted in seizures"
- "Concerta in increasing doses up to 54 mg per day. The patient described that he becomes more anxious, irritable, depressed, restless ... difficult to sleep ... dry mouth and blurred vision ... tense throughout the body and had spasms in shoulders and arms"
- "Treatment with Concerta and Ritalin has been tried without effect."
- "Lack of effect of methylphenidate and relatively pronounced anxiety afternoon / evening."
- "Have tried Ritalin but had seizures."
- "received different doses of Ritalin to 40 mg per day and has not improved, at higher doses rather worsened."
- "Medicated with methylphenidate but previously developed a toxic hepatitis."

- "Ritalin. ... in quite a high dose (1.5 mg / kg / day) developed, however, after about three months of treatment auditory hallucinations that disappeared immediately after discontinuation"
- "Concerta ... troublesome side effects in terms of increased general anxiety that lasts all day, concentration problems, diarrhoea, great concern and anxiety, nervousness and depression and dysphoria and severe loss of appetite."
- "... Has tried Concerta, which only made her sad."
- "Concerta ... did not give an equally good effect ... patient lacks the distinctive sweep of the amphetamine effect compared with Concerta's discrete onset of action. "
- "Ritalin capsule... but after four days responded with sharp rise in blood pressure ..."
- "Ritalin and Concerta has led to increased tics and Strattera has not had the desired effect over time."
- "... Concerta gave nausea, fainting and dyspepsia."
- "Concerta ... after about a year ago began to perceive an emotional impact that is an unpleasant side effect of Concerta and stopped."
- "Concerta T reacted with fatigue, increased compulsion, and sleep disturbances."
- "Could not stand Concerta due to side effects became aggressive."
- "... Previously tried the long-acting central stimulants medications including Concerta tablet but this has not worked at all."
- "Ritalin dose that gives rise to anxiety"
- "Concerta ... experienced troublesome side effects such as joint pain, muscle pain and swelling in the legs. These symptoms subside the days she does not take her Concerta. "
- "Ritalin SR ... suffered severe side effects such as nausea, which made it impossible to continue treatment."
- "Treatment with Concerta, but with very minimal effect."
- "Ritalin was rather more hyperactive and distracted. ... Concerta... once again became more hyperactive and distracted."
- "Concerta not been successful"
- "Concerta. ... No good effect of the drug and he feels mostly tired."
- "Tried Concerta, but was less effective and possible side effects of rash."
- "Concerta escalation of doses, Atomoxetine, Reboxetine and Ritalin capsule and also Tabl. Ritalin in different doses without any particularly good effect on the patient's symptoms. "
- "Initially Ritalin, which however did not work very well. ... Concerta with the same results Strattera did not work at all, but pronounced impulsivity and increased conflict."
- "Methylphenidate and atomoxetine later without effect "
- "... Failed to respond to methylphenidate."
- "... Both tried Concerta, and Strattera Ritalin. During treatment with Methylphenidate, he became more anxious and restless and his impulsive acts deteriorated. During Strattera, he was totally confused for a short time and stopped immediately. "
- "Ritalin ... Moderate effect on core symptoms of ADHD, but side effects such as severe compulsion and developed phobias. Disappeared after discontinuation."
- "Concerta ... not worked at all."
- "Previous treatment trials with Concerta and Ritalin in the maximum dose did not provide effect."
- "Tried Concerta but he had side effects of this in terms of constant high pulse."
- "Ritalin ... got his impulsivity back. He is very afraid he will harm his children at such occasions. "
- "Tried Ritalin, vulnerable because of side effects."
- "... tried Ritalin, but was clearly sad by treatment and was not feeling well."
- "... Tried both Concerta and Ritalin, but then experienced difficulties to relax."
- "Concerta up to 36 mg ... gave no effect on patient symptomatology ... feeling still tired and distracted ..."
- "... tried other stimulants as Ritalin and Concerta, but the effect has not been satisfactory."
- "... Ritalin 40 mg it was hard to tolerate."
- "On Concerta treatment ... he got many tics. We are now trying to combine Amphetamine-treatment with a low dose of Concerta ... "
- "... been on Concerta up to 72 mg and now on Ritalin 120mg. None of these preparations have had adequate effect. "

- "Ritalin and Concerta ... have been tried without positive effect."
- "... Previously tried Concerta but felt completely paralyzed by the drug."
- "Methylphenidate and atomoxetine have unacceptable side effects such as headache and abdominal pain."
- "Treatment attempts were made with Concerta ... became more compulsive and restless. "
- "Concerta ... severe stomach problems"
- "...treatment trials of Concerta, Ritalin and Strattera have reacted with strong ... hyperactivity, defiance, and possibly mania."
- Ritalin & Zoloft "insufficient effect"
- "Ritalin / Concerta without satisfactory effect"
- Concerta and Ritalin. "Residual effects in the form of very powerful, almost physical anguish. Palpitations, numbness and tremors. Earlier tried Strattera without effect. "
- "Patient has been treated with methylphenidate in increasing doses, without significant clinical effect at lower doses and severe side effects such as increased agitation, sleep disturbance, muscle aches and tachycardia at doses above 30 mg."
- "Concerta up to 72mg. Is improved but have gone down very much in weight and have trouble sleeping. "
- "Tried Ritalin, Concerta and Strattera without success."
- "Earlier treatment trial...Concerta and Ritalin for several years proved insufficient effect."
- "Tried methylphenidate but due to of insufficient efficacy and side effects now been on Metamina over half a year."
- "Concerta has been tested in dose increase to 54mg/d with some effect, but growing anxiety. A switch to Strattera, which already at a low dose resulted in severe nausea, dizziness and loss of appetite."
- "Tried both Concerta and Strattera, but abandoned both treatments due to side effects, despite a good effect on ADHD symptoms. "Concerta dysphoria and anxiety. Strattera sexual problems."
- Concerta. "Perennial history of depressive illness ... Concerta, but given the side effects such as agitation, anxiety and insomnia, stressed feeling. Had these side effects even at low dosage"
- Ritalin, Equasym, Strattera. "Some, but not enough effect ... side effects of both Strattera and CS [central stimulants]. "
- "The effect of Ritalin has been limited and the patient has also become more depressed."
- Concerta. "Bothersome dry cough which is clearly related to this medication."
- "We've tried with different stimulants such as Concerta and others. The results were very meager. "
- Strattera and Ritalin. (Ritalin), "pulse rise that is troublesome and he may also get an increased tic problem which is also troublesome, ... Pulse increase has been around 100 beats per minute instead of the normal resting heart rate around 70 in both controls by nurses and doctors. "
- "Tried Ritalin which made her depressed."
- Methylphenidate. "Got troublesome side effects."
- Concerta, Ritalin. "Allergic reactions in the form of shortness of breath."
- Treatment for depression, "not improved by the comprehensive treatment ... methylphenidate in gently increasing dose but responded with nausea, dizziness, feeling stress, which can easily escalate to severe anxiety, which has made increasing the dose of 45mg Concerta impossible." ... Experiment with the addition of Strattera has also been made without positive effect. "
- Methylphenidate. "After examination, the patient treated with methylphenidate, dose about 60mg positive effect. The patient thinks that the effect is insufficient and would therefore want to try Metamina instead. "
- Concerta, Ritalin. "...was discontinued due to a suspected allergic reaction."
- "Ritalin ... arose reaction (rash, itching), Strattera is not successful: sleep problems, emotional blunting"
- "Not previously tolerated Concerta."
- "Maximum dose of Concerta was 72 mg and the maximum dose of Ritalin was 40mg 2 in the morning ... In higher doses, he has been rather over-stimulated, without reaching full symptomatic relief. "
- "Ritalin and Concerta, which had to be discontinued due to side effects."

- "...we notice that the effect of Concerta 2 pills 36 mg daily is inadequate ... We have had to increase the dose Concerta, been up to 126mg daily, and she has also got the addition of Ritalin in pill form, but continues to experience tremendous fatigue and difficulty starting. By now wondering ...if Metamina may be an option ... Due to insufficient efficacy of methylphenidate wish to test the Metamina in order to optimize (!) the treatment as the patient experiences hopelessness as regards the bettering of her condition."
- Concerta, Ritalin, Strattera. "The patient has not been able to continue with these medications due to side effects of the preparations, and sometimes because he had no benefit from them ... one may give the patient a chance to try Metamina too."
- "Strattera, Concerta and Ritalin is not giving effect ..."
- "Treatment trials with methylphenidate up to 90mg daily, a relatively high dose given that the patient weighs about 60 kg. Medication had no significant effect, so the test was discontinued after a few months ... internal stress and significant difficulties in getting started with tasks and complete unfinished projects prevents both work ... social contacts ... do treatment trials with Metamina."
- Concerta and Strattera. "Had to be terminated due to depression, insomnia and a feeling that does not recognize himself."
- Methylphenidate. "Difficult to evaluate the treatment ... What he particularly seems to have achieved is an improved ability to handle the contact with 'difficult people'... Side effects occur in the form of headaches, motion sickness-like nausea...Furthermore, the patient ticlike blinking of a similar level."
- Ritalin. "His motor tics got worse and he also got side effects in form of double vision"
- "Tried all of central stimulant drugs on the market in Sweden, but without the desired effect and side effect severe headache."
- "Only a small effect of Ritalin"
- Methylphenidate and antidepressants. "An adequate dose has had limited effect."
- Methylphenidate. "Got...intolerable side effects."
- Concerta "not significantly positive result"
- Concerta and Ritalin. "...intolerable side effects such as anxiety, nausea, increased pain and fatigue." With Metamina "improvement in endurance."
- Methylphenidate "without experiencing a satisfactory effect"
- Concerta "effect .. decreased ... associated with depression"
- Concerta and Ritalin. "Side effects"
- Methylphenidate "without enough effect"
- Concerta, Ritalin. "had to end this after a few months because of severe side effects such as muscle and joint pain, uncommunicativeness and suicidal thoughts ... I tried Ritalin ... same side effects, although to a lesser extent."
- Concerta "without any significant effect"
- Ritalin "discontinued because of side effects "
- Concerta "largely ineffective"
- Concerta, Ritalin "annoyed by muscular side effects, he clearly puts in connection with the medication."
- Ritalin "with side ... increased muscle tone, abdominal pain"
- "Ritalin 40mg in the morning, Metamina T 0 +3 +3"
- "Necessary to bring the day to work"
- Methylphenidate "gave...dermatitis"
- Methylphenidate "became hyper-focused in some way"
- Ritalin "palpitations and muscle pain "
- Ritalin, Strattera. (Ritalin) effects completely subsided. Gives lowering of mood. "
- Methylphenidate "at 3.5-4 tablets very good effect, but at the same time grandiose feeling."
- Methylphenidate "no beneficial effect"
- Methylphenidate "not given adequate effect, but with side effects in the form of fever, blurred vision."
- "Tried similar products to Metamina but had not sufficient effect"
- Ritalin "insufficient treatment effect resulted in more side effects, palpation, fatigue, poor concentration skills clearly with Ritalin. "

- "Strattera has not worked. Concerta, Ritalin works but may display adverse reactions in the form of particular anxiety why it has been difficult to take the medication in the dose he would need."
- "Absent effect of both Ritalin and Concerta" (dose up to 100mg in previous treatment)
- "Treatment with Metamina discontinued because of obvious difficulties with compliance ... even committed crimes ... treatment in hospital for an unspecified time ...wish it now, under more controlled conditions to resume treatment with Metamina."
- "Concerta...gave a lot of side effects."
- "Concerta and Ritalin without effect."
- "Emotional unstable personality disorder, recurrent depression and ADHD ... tested Concerta, Ritalin and Strattera, without success. Primarily got side effects."
- "Methylphenidate ... developed relatively troublesome side effects in the form of mainly abdominal discomfort, nausea and vomiting."
- "Tried to medicate approved preparations without significant effect."
- "Concerta / Ritalin gave lots of uncharacteristic side effects."
- "For which Ritalin was not working and have had adverse reactions."
- "Methylphenidate previously tested with considerably less effect."
- "Methylphenidate ... effect was insufficient. Adverse reactions, irritability, anxiety, impaired verbal flow. "
- "Methylphenidate ... many side effects such as gastrointestinal upset, malaise, apathy, muscle cramps... history of many years of abuse of amphetamines, in small doses...Dose: 100 mg /day"
- "72mg Concerta without significant effect and with increased anxiety, even panic attacks ... Given the patient's very ambitious and recurring experiences of failures and unfinished projects, it is considered of great value to her to make a treatment trial with Metamina."
- "Concerta and Ritalin have been stopped due to side effects in the form of...depression and increasing anxiety, and inadequate efficacy"
- "Concerta ... dizziness and low blood pressure."
- "Formerly with Concerta, Ritalin and Strattera without effect."
- "Significantly more side effects from methylphenidate and much less effective."
- "Ritalin ... elevated heart rate was unacceptably high."
- "For a short period self-medicated with small doses of amphetamine and the better she felt."
- "Ritalin and Concerta ... intolerable side effects ... sudden emotional swings from high happiness to sadness and tears. Strattera was tested which gave great concern and anxiety."
- "Concerta and Ritalin ... implied a positive effect in terms of reducing anxiety. In raising the dose ... headache, increased sweating, indigestion, and some increase in anxiety."
- "Concerta ... severe side effects as nausea and increasing abdominal discomfort. Changed since Ritalin dose up to 140mg daily. Has left much of the difficulty in concentration, despite this dose ... would like to try Metamina treatment... was also found...recurrent depression, emotionally unstable personality ... also a polydrug use."
- "Tried Ritalin and Concerta, but had no good effect, however, a lot of troublesome side effects, with headache, increased anxiety and memory disorders."
- "Concerta ... bad effect and headache."
- "Ritalin ... 110mg ... not had full effect ... experience some residual attention deficit disorder."
- "Diagnosis of recurrent depression ... tried all the treatments available to us including SSRIs, tricyclic drugs, MAOIs, ECT, and various combination treatments ... no treatment trial gave a significant effect."
- "Methylphenidate ... sensitive, insecure, paranoid feelings implied in the higher dose."
- "Tried both Ritalin and Concerta and had very high doses, however not felt totally helped and is now set to Metamina in the above dosage ... question is whether she now needs to increase the dose." Dose 80mg/dag
- "Tried both Strattera to Ritalin and Concerta without any effect. On the other hand ... a lot of side effects. "
- "Tried Concerta, Ritalin and Strattera and all with pretty bad results."
- "... Concerta side effect in the form of headache which patient even at a couple of occasions had been confined to bed."
- "Tried both Ritalin, Concerta and Strattera ... allergic reaction on both Concerta and Ritalin. Strattera did not have any effect except to increase the patient's anxiety."

- "Concerta then Strattera... without clear effect, however, with troublesome side effects (agitation, irritability, sleep disturbance). Subsequently put on Amphetamine ... despite dose adjustments have had increasing problems associated with coming down (!) at any doses, especially after the last dose (rapid severe mood swings, increased psychological fatigue, poor concentration) ... As dextroamphetamine have slightly longer half-life and better half-life than amphetamine the coming-down period (!) can be tolerated better... The patient should have the opportunity to test dextroamphetamine. "
- "Ritalin ... was discontinued for about a week due to increased aggression ... Also tried with Concerta but also then got increased aggressiveness in a similar manner as with Ritalin."
- "Tried every drug on the market available to for his disability ... Ritalin, then ... tried Concerta long-acting Ritalin, as well as Equasym Depot, with side effects such as loss of appetite and insomnia. Also felt anxious and depressed ... tried Strattera ... very moderate effect ... tried combining Strattera 60mg (evenings) with 36mg Concerta in the morning ... there are experiences among practitioners colleagues (in both child and adult psychiatry) that Metamina can work a little bit better in this patient group [ADHD, Asperger's]."
- "For many years in maintenance treatment for opiate dependence ... currently Methadone ... also diagnosed with ADHD ... medicated with Strattera ... was not feeling well from this and have been prescribed Concerta ... works well during the day but makes him uneasy in the late afternoon. ... he has tried both amphetamine and Metamina and describes the effect of this that it has the advantage that it disappears in the afternoon and make him sleep well at night ... therapy trial with Metamina." Dose "increase to the appropriate level".
- "Concerta increase without significant effect, then Ritalin increase to 50mgx4!, With some effect, but not optimum ... Also tried Strattera, which the patient has not tolerated, nor been able to wait for effect due to earlier irritability returned. Wish now to try Metamina, as I could not get the full effect of methylphenidate, despite extreme doses. "
- "Treated with short-acting Ritalin, Concerta, and with the two preparations in combination, and troubled by a sense of medication influence, why he wishes to try Metamina."
- "Patient has a history of depression fatigue probably due to her ADHD problems."
- "Both Concerta and Ritalin has caused severe side effects such as nausea, vomiting, weight loss, anxiety and depression."
- "Earlier a multi-year dependence on amphetamines ... medicated with methylphenidate, Concerta earlier, now Ritalin ... not felt good, is irritable, depressed. Examined the addition of antidepressants, Sertalin, Cymbalta, even tested Lamictal without any improvement of mood."
- "Concerta with insufficient effect, and had increased anxiety ... now applying for a license for Metamina to optimize the effect of CS." N
- "Metamina dosage has been increased to 11-13 [55-65mg] tablets a day."
- "Diagnosis fatigue syndrome, generalized anxiety disorder treated with Metamina as Ritalin has not given effect and causes side effects."
- "tried Concerta and Strattera but reacted with severe side effects."
- "Medication with methylphenidate ... had to be discontinued at a relatively low level due to anxiety attacks ... even an attempt with Strattera ... discontinued for the same reasons as before."
- "Tried T Metamin in increasing dose."
- "Concerta resulted in insomnia and anxiety, and changing to Strattera resulted in increased anxiety."
- "Tried Ritalin and Concerta respectively and improved significantly concerning concentration. Had to discontinue both treatments due to very difficult adverse side effects."
- "Now on Concerta, but can not take more than 18-36mg/dag, giving insufficient effect. If she takes more she gets palpitations and becomes sick. "
- "Treated with methylphenidate, up to 70mg/d positive results but clearly insufficient effect. Why switch to Metamina is recommended."
- "Treated with methylphenidate ... The effect has been poor, only positive effect has been that she has not been so irritable."
- "Methylphenidate without effect."
- "Treated with methylphenidate in relatively high doses. 70mg/d without adequate efficacy and side effects in form of tachycardia and tremour. "
- "Examined at our specialist clinic for addiction disorders and he has been prescribed Ritalin and then he developed a psychosis which led to care in our intensive care department ... switch to Concerta improved .. could be managed in outpatient settings. He has experienced a

non-sound effect of Concerta why we are now seeking Metamina... previously treated with high doses of Ritalin and Concerta (216mg per day) without real effect. ”

- ”Tried the treatment with all the options available: Concerta, Equasym, Ritalin, but the effect has not been there and patient had a lot of side effects.”
- ”Dosage 8 +8 +8 DAILY” gives 120mg Metamina per day.
- ”Metamina ... contributed to an increase in waking, reduced start-up difficulties, which made life more bearable for the patient.”
- ”Tried Ritalin and Concerta, but was not happy when he took those preparations ... Strattera a good effect on ADHD ... stomach pain ... The pain got worse.” (School-age children)
- ”Tried methylphenidate, which has not helped, and gave reactions at moderate dose.”
- ”Diagnosis: Protracted severe depression ... bipolar disorder, with primarily very lengthy and difficult to treat chronic depression ... suicide risk ... treated with a wide range of psychotropic drugs without any tangible positive results. Earlier possibly some effect of ECT ... ordained forced medication with ECT. Since November methylphenidate with a weak to possibly small effect. To this difficult to treat patient, I think it's worth making an effort with Metamina when we have so far failed to help her with any other medicine. ”
- ”Not had adequate efficacy with antidepressants ... trying Concerta and Ritalin, and he felt the effect on concentration and work. Pretty soon, he gets anxiety, depression, sadness of life... Patient can probably find it helpful to test Metamina. ”
- ”Concerta 18mg. Increased debilitating anxiety ... Some nights ... could not sleep at all. ”
- ”Incomplete response to Ritalin in high doses.”
- ”Methylphenidate ... not optimum effect ... was troubled by repeated anxiety attacks ... Not offered support in medication ... relapse to amphetamine use ... detoxified...important that he be given the opportunity to try Metamina. Methylphenidate has given adverse events in form of deep depression with apathy, lack of confidence in the future. ”Dose 15-18 tablets per day” [75-90mg]
- ”Tried both Ritalin and Concerta... moderate efficacy, side effect in form of depression, discomfort.” Metamina ”18-20 tablets a day” [90-100mg]
- ”Constant tendency to push forward various projects ... talented and high probability is that he with adequate treatment with stimulants would have a better chance to cope with these ... methylphenidate tested and got... anxiety and worry.”
- ”Ritalin ... severe side effects such as palpitations, headaches, increased anxiety, loss of appetite and difficulty sleeping.”
- ”Tried both Strattera and Ritalin but had intolerable side-effects.”
- ”Tried Ritalin with bad effect.”
- ”Concerta resulted in severe anxiety ... Ritalin as yet yielded no effect. When the dose was increased the patient got anxiety and reinforcement of aggressive feelings. Plan to start with dexampfetamine sulphate [Metamina]. ”
- ”Medicated with Concerta with poor treatment outcomes.”
- ”Complex psychiatric problems both with an emotionally unstable personality, past alcohol and drug abuse in combination with ADHD ... In recent times ... had a few relapses, drunk alcohol and smoked cannabis. Despite this, the patient experienced a decrease in drug want when she takes stimulants ... very important that the patient may continue with Metamina. ”
- ”... Family history of ADHD... treatment with Ritalin. It turned out that patient was slightly depressed, leading to that patient got treatment with antidepressants. It turned out ultimately that patient is not very depressed and that her symptoms can be fully explained by the basic diagnosis of ADHD ... tried unsuccessfully treated with T Concerta 36mg/dygn ... not tolerate T Strattera. ”
- ”Tried methylphenidate but developed side effects with increased anxiety, feeling of being drug influenced and strong itching.”
- ”Concerta in dose up to 54 mg/day ... depressed mood and feeling of being screened off ... Ritalin ... had recurring problems with blurred vision and double vision ... ophthalmologist ... 'some accommodation influence can be caused by Ritalin' ”
- ”Tried adequate doses of Concerta and Ritalin and had side effects such as anxiety, when the medication effect subsided. Even tried Strattera, but had major side effects.”
- ”Treated with Ritalin in high dose (160mg/d) ... Very good treatment outcomes but, strong anorexia ... lost weight from 64 to 54 kg. Lower dose has been tried... absence of the positive effect of methylphenidate. ”

- "Concerta and Ritalin, both of which resulted in many adverse reactions in the form of anxiety and palpitations."
- "ADHD and drug dependence in remission ... In the past, treatment trials done with Concerta, Ritalin and Strattera. The patient has shown sharp and unexpected side effects with all treatments (ranging from allergies to hallucinations). A last attempt to treat the patient's restlessness is planned with Metamina. "
- "Concerta ... got behavioral disturbances. Switched to Ritalin but got depressed thoughts, became more impulsive, intoxicated with Ritalin tablets 5 pieces ... On another occasion, climbed up on the facade on a high building on the roof. Inhibitions were completely missing and he had a kind of high feeling in the body ... tested with Strattera treatment and was up at 40 mg when he received somatic side effects such as severe fatigue, sleepiness, severe abdominal pain, flu-esteeem, varying activity level, etc. "
- "Tried both T Concerta and T Ritalin without effect...severe side effects were noted."
- "A hefty ADHD as well as related amphetamine abuse ... tried both Concerta and Ritalin. Concerta did not work at all as he got psychotic experiences. Ritalin tested also in reasonable hefty doses without adequate effect. Two serious suicide attempt last month and I can not see that we can refrain from also trying Metamina when it almost feels like the last opportunity to save his life. "
- "Trials with Concerta has been done... increase up to 36 mg without effect...numbness, dizziness and headache"
- "Concerta treatment ... get uncomfortable side effects of dizziness."
- "Medication also with 12 mg of Subutex." Dosage 12 tablets 3 times daily (180mg)
- "Tried Ritalina and Concerta, but experienced severe side effects."
- "Concerta ... dose 54 mg in the morning and 18 mg in the day ... not particularly good effect on his mood and his ability to concentrate. He wants to test Amphetamine. "
- "Methylphenidate has had moderate, clearly insufficient effect why treatment with dexamphetamine is recommended."
- "Concerta slow dose increase up to 54 mg. Initially the patient experienced a good mood, he became calmer, he could sit still and less impulse breakthrough. When the dose was not sufficient for the afternoon, dose increase to 54 mg in the morning and 54 mg in the afternoon ... still had a hard time in the afternoon / evening, we raised the dose to 162 mg ... still did not have significant improvement or effect we transferred him to the capsule of Ritalin...with gradual dose increase to 160 mg ... relapsed, however, in an alcohol abuse ... New assault and binge ... put in Medikinet dose of 160 mg with an improvement in concentration, and restlessness, but the patient experienced headache, which disappeared when the medicine was discontinued which led to the cognitive deterioration coming back. "Dosage 14 tablets, 70 mg.
- "Tried all on the market available methylphenidate preparations such as Medikinet, Ritalin, Concerta and also Atomoxetine - Strattera. All preparations have given him side effects and he has not seen any good effect of any of these. "
- "Concerta treatment with bad results."
- "Previous abuse history is ... iatrogenic benzodiazepine dependence ... tried Concerta up to 36 mg with severe side effects such as irritability, depression of mood state, and fatigue combined with sleep disturbance, he discontinued himself."
- "Concerta has been inadequate."
- "Tried Concerta and Ritalin (methylphenidate) but have had a rash and had no effect. Is as restless as ever. "
- "Ritalin, Concerta and Strattera had insufficient efficacy and unacceptable side effects."
- "...on the medication Concerta 7 x 36 mg + 18 mg, which seems to be insufficient in effect." (270 mg of Concerta a day)
- "Concerta with no effect, however, with very strong side effects."
- "Ritalin ... The effect has been insufficient, also troublesome side effects."
- "Tried treatment with Ritalin, but not tolerated this, become more speeded up, aggressive, etc."