

*newsletter*

## Psychoactive drugs for children

**Recent years have seen a sharp increase in the number of children treated with methylphenidate (Ritalin<sup>®</sup>, Medikinet<sup>®</sup>), a drug used in attention deficit hyperactivity disorder. In addition to prescribing practice and the controversial diagnostic criteria, the drug's increasing misuse is also a cause of debate among experts.**

### **General, Ritalin<sup>®</sup> use in children**

Methylphenidate (Ritalin<sup>®</sup>, Medikinet<sup>®</sup>) has been used for over 50 years in children with attention deficit (ADHD). In Germany sales have increased over 40-fold in recent years, and it is estimated that in the US alone 6–8 million children are taking Ritalin<sup>®</sup>. Experts warn of the need to beware of overdiagnosis and curb overuse of this compound.

### **ADHD, methylphenidat**

ADHD was first described medically in 1902. It consists of defective concentration and hyperactivity occurring mainly in school-age children. Boys are 8 times more affected than girls. The diagnosis of ADHD is complex. It is based on the evaluation of small-scale deviations from behaviours that, to a certain extent, are present in all children. A further complication is that ADHD often coexists with other disorders having similar symptoms (eg depression, personality disorders). It is thus highly probable that methylphenidate is also used in children whose abnormal behaviour has other causes. Ritalin<sup>®</sup> is the most widely prescribed drug in ADHD cases. Its active substance is methyl- $\alpha$ -phenyl-2-piperidineacetate hydrochloride. It is a prescription-only medication and in Germany it is subject to the narcotics law. For this reason doctors are required to report each prescription they write. Ritalin<sup>®</sup> is a stimulant and has pharmacological effects similar to those of cocaine and amphetamines. In the US it is classified as a category 2 controlled substance together, for example, with morphine, cocaine and methadone. Its precise mechanism of action is not yet understood. However, it is known that it is not a curative agent. Methylphenidate relieves complaints only for as long as it remains in the body. If the level falls (the mean half-life of methylphenidate is 2 hours), the pre-treatment situation returns.

<b>Side effects</b>	Ritalin <sup>®</sup> can produce some unpleasant physical and psychological symptoms, ranging from weight loss, headache, elevated blood pressure, and muscle twitching (tics) to cardiac arrhythmia and hallucinations. Although it has been used for over 50 years, adequate data on long-term use in children are not yet available.
<b>Abuse</b>	In addition to its use as a prescription drug, methylphenidate is swallowed, sniffed in powdered form or injected intravenously, ie it is subject to abuse as a stimulant. There is a flourishing black market, especially in the school setting, in which Ritalin <sup>®</sup> is sold, in Germany for example, as “cheap coke” or “vitamin R”. Oral ingestion causes marked psychological, but no physical dependence. For this reason the Drug Enforcement Administration (DEA) and World Health Organization (WHO) classify Ritalin <sup>®</sup> as a drug of abuse.
<b>Conclusion</b>	Methylphenidate (Ritalin <sup>®</sup> , Medikinet <sup>®</sup> ) belongs to a group of medicines known as stimulants which have long been used in children with ADHD. The number of prescriptions has risen sharply in recent years – a development which experts criticise, not least due to the complex diagnostic criteria. Nor do we yet know the precise effect that methylphenidate has on the child’s still developing brain. There are no systematic long-term studies available.
<b>Information for the underwriter</b>	The relevance for underwriting relates mainly to product liability and recall, given the drastic increase in the number of children being treated with a psychoactive drug whose long-term effects are unknown and whose medical indications are open to dispute. Indeed, a class action against the manufacturer Novartis – accused of working on the definition of ADHD in order to sell its Ritalin <sup>®</sup> product – was only recently dismissed in the US. However, further actions are perfectly conceivable. Recalls are also conceivable if backed by the results of long-term studies. In Sweden, for example, Ritalin <sup>®</sup> has recently been banned and each treatment must be individually approved by the authorities. The Swedish medicines agency guidelines require the application to be made in writing and justified in detail. There is a further claims potential in the possibility that Ritalin <sup>®</sup> can be obtained via the Internet where it would be impossible to check the amounts being acquired, there would be with no medical indication or supervision and no explanations of the risks.

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