Attenta

Methylphenidate hydrochloride

PRODUCT INFORMATION

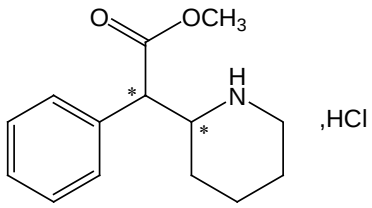
Drug Dependence: Attenta should be given cautiously to patients with a history of drug or alcohol dependence. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Name of the Medicine

Active ingredient: Methylphenidate hydrochloride

Chemical name: 2-piperidineacetic acid, α-phenyl-, methyl ester, hydrochloride, (*R**,*R**)-(±)-

Structural formula:



Molecular formula: $C_{14}H_{19}NO_2.HCl$ Molecular weight: 269.77

CAS Registry No.: 298-59-9

Description

Methylphenidate hydrochloride is a white, odourless, fine crystalline powder. Its solutions are acid to litmus. It is freely soluble in water and in methanol, soluble in alcohol, slightly soluble in chloroform and in acetone.

Each tablet contains 10 mg of methylphenidate hydrochloride. The tablets also contain lactose, starch - maize and magnesium stearate. *The tablets are gluten free.*

Pharmacology

Methylphenidate is a central nervous stimulant. Its mode of action in humans is not completely understood, but methylphenidate presumably exerts its stimulant effect by activating the brainstem arousal system and cortex. There is neither specific evidence which clearly establishes the mechanism whereby methylphenidate produces its mental and behavioural effects in children, nor conclusive evidence as to how these effects relate to the condition of the central nervous system.

Pharmacokinetics

Absorption. Following oral administration of the tablets, the active substance (methylphenidate hydrochloride) is rapidly and almost completely absorbed. Owing to extensive first-pass metabolism, its systemic availability amounts to only 30% (11 to 51%) of the dose. Ingestion together with food accelerates its absorption, but has

no influence on the amount absorbed. Peak plasma concentrations of approximately 11 nanogram/mL are attained, on the average, two hours after administration of 0.3 mg/kg. The peak plasma concentrations, however, vary markedly from one person to another. The area under the plasma concentration curve (AUC), as well as the peak plasma concentration, are proportional to the size of the dose administered.

Distribution. In the blood, methylphenidate and its metabolites become distributed in the plasma (57%) and the erythrocytes (43%). Methylphenidate and its metabolites have low plasma protein binding (approximately 15%). The apparent volume of distribution has been calculated at 13.1 L/kg.

Metabolism and Excretion. Methylphenidate is eliminated from the plasma with a mean half-life of two to three hours, and the calculated mean systemic clearance is 4 to 10 L/hour/kg. Within 48 to 96 hours, 78 to 97% of the dose administered is excreted in the urine, and 1 to 3% in the faeces, in the form of metabolites. Unchanged methylphenidate appears in the urine only in small quantities (<1%). The bulk of the dose is excreted in the urine as alpha-phenyl-2-piperidyl acetic acid (PPAA, 60 to 86%). Peak plasma concentrations of PPAA are attained about two hours after administration of methylphenidate and are 30 to 50 times higher than those of the unchanged substance. The half-life of PPAA is roughly twice as long as that of methylphenidate.

There are no apparent differences in the pharmacokinetic behaviour of methylphenidate in hyperactive children and normal adults.

Indications

Attention Deficit Hyperactivity Disorder (ADHD)

ADHD was previously known as attention deficit disorder. Other terms being used to describe this behavioural syndrome include minimal brain dysfunction in children, hyperkinetic child syndrome, minimal brain damage, minimal cerebral dysfunction, minor cerebral dysfunction, and psycho-organic syndrome of children.

Attenta is indicated as part of a comprehensive treatment program which typically includes other remedial measures (psychological, educational, social) for achieving a beneficial effect in children with a behavioural syndrome characterised by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity (not always present) and impulsivity. The diagnosis of this syndrome should not be made when these symptoms are only of recent origin. Non-localising (soft) neurological signs, emotional lability, learning disability and an abnormal electroencephalogram (EEG) may or may not be present, and a diagnosis of CNS dysfunction may or may not be warranted.

Special Diagnostic Considerations for ADHD. The aetiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but also of psychological, educational and social resources. Characteristics commonly reported include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and an abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in children who exhibit symptoms secondary to environmental factors (e.g. child abuse in particular) or primary psychiatric disorders. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the doctor's assessment of the chronicity and severity of the child's symptoms.

Narcolepsy

The symptoms include daytime sleepiness, inappropriate sleep episodes and rapidly occurring loss of voluntary muscle tone. Effective for symptoms of sleepiness but not for loss of voluntary muscle tone.

Contraindications

Attenta is contraindicated in patients with the following:

- anxiety and tension states
- agitation
- tics
- tics in siblings
- a family history or diagnosis of Tourette's syndrome
- glaucoma
- hyperthyroidism
- cardiac arrhythmia
- severe angina pectoris
- treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result)
- known hypersensitivity to methylphenidate or any component of the formulation
- phaeochromocytoma
- known drug dependence or alcohol abuse
- uncontrolled hypertension
- ischaemic heart disease
- myocardial infarction
- severe depression, anorexia nervosa, psychotic-symptoms or suicidal tendency, since Attenta might worsen these conditions.

Precautions

Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents
Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug.

Adults
Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs.

It is essential that children, adolescents, or adults with pre-existing structural cardiac abnormalities or other serious heart problems being considered for treatment are assessed by a cardiologist before initiating treatment. Ongoing cardiological supervision should be maintained throughout treatment in these patients.

Cardiovascular Conditions

Attenta generally should not be used in patients with severe hypertension. Attenta increases heart rate and systolic and diastolic blood pressure. Therefore, caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g. those with pre-existing hypertension, heart failure, recent myocardial infarction, atherosclerosis. Cardiac arrhythmia and severe angina pectoris are contraindicated (see **Contraindications**). Attenta should be used cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in all patients taking methylphenidate, especially in those with hypertension.

Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease. Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

Misuse and Cardiovascular Events

Misuse of CNS stimulants may be associated with sudden death and other serious cardiovascular adverse events.

Cerebrovascular conditions

Patients with pre-existing CNS abnormalities, e.g., cerebral aneurysm and/or other vascular abnormalities such as vasculitis or pre-existing stroke should not be treated with Attenta. Patients with additional risk factors (history of cardiovascular disease, concomitant medications that elevate blood pressure) should be assessed regularly for neurological/psychiatric signs and symptoms after initiating treatment with Attenta (see **Precautions - Cardiovascular Conditions**).

Psychiatric conditions

Attenta should not be used to treat severe depression or for the prevention or treatment of normal fatigue states. In psychotic patients administration of methylphenidate may exacerbate symptoms of behaviour disturbance and thought disorder.

Co-morbidity of psychiatric disorders in ADHD is common and should be taken into account when prescribing stimulant product. Treatment of ADHD with stimulant products including Attenta should not be initiated in patients with acute psychosis, acute mania, or acute suicidality. These acute conditions should be treated and controlled before ADHD treatment is considered.

Methylphenidate should not be used as treatment for severe depression of either exogenous or endogenous origin.

In the case of emergent psychiatric symptoms or exacerbation of pre-existing psychiatric symptoms, Attenta should not be given to patients unless the benefit outweighs the potential risk.

Psychotic symptoms

Psychotic symptoms, including visual and tactile hallucinations have been reported in patients administered usual prescribed doses of stimulant products, including methylphenidate (see **Adverse Effects**). Physicians should consider treatment discontinuation if psychotic symptoms occur.

Bipolar Illness

Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/manic episode in such patients.

Aggressive behaviour

Emergent aggressive behaviour or a worsening of baseline aggressive behaviour has been reported during stimulant therapy. However patients with ADHD may experience aggression as part of their medical condition. Therefore, causal association with treatment is difficult to assess. Physicians should evaluate the need for adjustment of treatment regimen in patients experiencing these behavioural changes, bearing in mind that upwards or downwards titration may be appropriate.

Suicidal tendency

Patients with emergent suicidal ideation and behaviour during treatment for ADHD should be evaluated immediately by their physician. The physician should initiate appropriate treatment of the underlying psychiatric condition and consider a possible change in the ADHD treatment regimen.

Fatigue

Attenta should not be employed for the prevention or treatment of normal fatigue states.

Seizures

There is some clinical evidence that methylphenidate may lower the convulsion threshold in patients with a history of seizures, with prior EEG abnormalities in the absence of seizures and rarely, in the absence of a history of seizures and no prior EEG evidence of seizures. Safe concomitant use of anticonvulsants and methylphenidate has not been established. In the presence of seizures, the drug should be discontinued.

Drug Dependence

Attenta should be given cautiously to patients with a history of drug or alcohol dependence. Chronic abuse can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes may occur, especially in response to parenteral abuse. Methylphenidate abuse or dependence does not appear to be a problem in adolescents or adults who were treated with methylphenidate for ADHD as children.

Careful supervision is required during withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

Alcohol may exacerbate the CNS adverse reactions of psychoactive drugs, including methylphenidate. Therefore, it is advisable for patients to abstain from alcohol during treatment.

Treatment Considerations

Treatment with Attenta is not indicated in all cases of ADHD and should be considered only in the light of the complete history and evaluation of the child. The decision to prescribe Attenta should depend on the doctor's assessment of the chronicity and severity of the child's symptoms and their appropriateness to his or her age. Prescription should not depend solely on the presence of isolated behavioural characteristics. When the symptoms are associated with acute stress reactions, treatment with Attenta is usually not indicated.

Long-Term Use

Data on the safety and efficacy of long-term use of methylphenidate are not complete. Therefore, patients requiring long-term therapy should be carefully monitored.

Laboratory Measurements

Periodic complete blood counts, differential and platelet counts are advisable during prolonged therapy.

Effect On Ability to Drive or Operate Machinery

Attenta may affect the patient's reactions and adversely influence his or her ability to drive and use machines.

Carcinogenicity

In a lifetime carcinogenicity study carried out in $B6C3F_1$ mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas at a daily dose of approximately 60 mg/kg/day. This dose is approximately 4 times the maximum recommended human dose of methylphenidate on a mg/m^2 basis. Hepatoblastoma is a relatively rare rodent malignant tumour type. The

mouse strain used is sensitive to the development of hepatic tumours, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increases in tumours in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 50 mg/kg/day, which is approximately 7 times the maximum recommended human dose of methylphenidate on a mg/m^2 basis.

In a 24-week carcinogenicity study in the transgenic mouse strain $p53^{+/-}$, there was no evidence of carcinogenicity. Male and female mice were fed diets containing the same concentration of methylphenidate as in the lifetime carcinogenicity study; approximately 60 and 74 mg/kg/day of methylphenidate, respectively, which is approximately 4 and 5 times the maximum recommended human dose of methylphenidate on a mg/m^2 basis, respectively.

Comment: The US Food and Drug Administration examined data from the Surveillance, Epidemiology and End Results (SEER) database for the years 1973 to 1991 and found that the estimated incidence of hepatoblastoma in the general population was not greater than 1 in 10 million person-years.

A total of 174 cases of hepatoblastoma were reported by the SEER for the period 1973 to 1995. The age-adjusted incidence rate is very low (IR=0.0382 per 100,000 person-years). The majority of cases (149 out of 174) were diagnosed among the age group 0 to 4 years old, which is in accordance with the natural history of the disease. For the age group 5 to 24 years old the rates of hepatoblastoma are very low with 14 cases reported. For the 0 to 4 years old age group, incidence rates of hepatoblastoma have risen slowly, ranging from 0.3032 per 100,000 in 1973 to 0.4889 per 100,000 in 1995. On the basis of experience since marketing methylphenidate, there is no evidence that the incidence is higher in patients receiving methylphenidate.

Genotoxicity

Methylphenidate was not mutagenic in assays *in vitro* (Ames reverse mutation assay and the mouse lymphoma cell forward mutation assay). Methylphenidate showed evidence of a weak clastogenic response *in vitro* (Chinese Hamster Ovary cells) but was negative *in vivo* (mouse bone marrow micronucleus assay).

Effects on fertility

Methylphenidate did not impair fertility in male or female mice that were fed diets containing the drug in an 18-week Continuous Breeding study. The study was conducted at doses up to 160 mg/kg/day, approximately 11-fold the highest recommended human dose of methylphenidate on a mg/m^2 basis.

Use in Pregnancy (Category B3)

As a general rule no drugs should be taken during the first three months of pregnancy, and the benefits and risks of taking drugs should be carefully considered throughout the whole of the pregnancy.

Adequate animal reproduction studies to establish safe use of methylphenidate during pregnancy have not been conducted. Oral administration of methylphenidate to rabbits during the period of organogenesis has produced teratogenic effects at systemic exposures (plasma AUC) approximately 3 times clinical exposure at the maximum recommended human dose. The exposure at the no-effect dose was less than human exposure. In rats, teratogenic effects were not seen at systemic exposures (plasma AUC) approximately 12 times clinical exposure at the maximum recommended human dose.

There are no adequate or well-controlled studies on the use of methylphenidate in pregnant women. Therefore, until more information is available, methylphenidate should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Australian categorisation of Category B3. Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.

Use in Lactation

It is not known whether the active ingredient of Attenta and/or its metabolites pass into breast milk. For safety reasons, mothers taking Attenta should refrain from breastfeeding their infants.

Paediatric Use

Attenta should not be used in children under 6 years, since safety and efficacy in this age group have not been established. Medicines should be kept out of the reach of children.

Long-term suppression of growth:
Long-term effects of methylphenidate in children are not available. Although a causal relationship has not been established, suppression of growth (i.e. weight gain and/or height) has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored. Patients who are not growing or gaining weight as expected should have their treatment interrupted.

Careful follow-up of weight and height in children aged 7 to 10 years who were randomised to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development.

Published data are inadequate to determine whether chronic use of amphetamines may cause similar suppression of growth; however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

Interactions with Other Medicines

Methylphenidate may decrease the effectiveness of drugs used to treat hypertension. Methylphenidate should be used with caution in patients being treated with drugs that elevate blood pressure including MAO inhibitors due to the risk of severe hypertension (see **Precautions - Cerebrovascular Conditions**).

As an inhibitor of dopamine reuptake, methylphenidate may be associated with pharmacodynamic interactions when coadministered with direct and indirect dopamine agonists (including DOPA and tricyclic antidepressants) as well as dopamine antagonists (antipsychotics, e.g. haloperidol). The coadministration of methylphenidate with antipsychotics is not recommended because of the counteracting mechanism of action.

Methylphenidate is not metabolised by cytochrome P450 to a clinically relevant extent. Inducers or inhibitors of cytochrome P450 are not expected to have any relevant impact on methylphenidate pharmacokinetics. Conversely, the *d*- and *l*- enantiomers of methylphenidate did not relevantly inhibit *in vitro* cytochrome P450 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 and 3A.

Methylphenidate coadministration did not increase plasma concentrations of the CYP2D6 substrate desipramine.

Case reports have shown that methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbitone, primidone, phenytoin), phenylbutazone and tricyclic antidepressants (imipramine, desipramine), but pharmacokinetic interactions were not confirmed when explored at higher sample sizes. Reduction in the dosage of these drugs may be required when they are given concomitantly with methylphenidate.

Serious adverse events have been reported in concomitant use with clonidine, although no causality for the combination has been established. The safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2 agonists has not been systematically evaluated.

Other specific drug-drug interaction studies with methylphenidate have not been performed *in vivo*.

Effects on Laboratory Tests

Methylphenidate may induce false positive laboratory tests for amphetamines, particularly with immunoassays screen test.

Adverse Effects

Post-Marketing Experience

Nervousness and insomnia are very common adverse reactions occurring at the beginning of the treatment and are usually controlled by reducing the dosage and omitting the drug in the afternoon or evening. Decreased appetite is also common but usually transient.

In children, loss of appetite, abdominal pain, insomnia and tachycardia may occur more frequently. However, any of the other adverse reactions listed below may also occur.

Adverse effects listed below are ranked under headings of frequency, using the following convention: very common ≥10%; common ≥1% to <10%; uncommon ≥0.1% to <1%; rare ≥0.01% to <0.1%, very rare <0.01%.

Immune system disorders

Very rare: hypersensitivity reaction.

Blood and lymphatic system disorders

Very rare: leucopenia, thrombocytopenia, anaemia.

Metabolism and nutrition disorders

Rare: moderately reduced weight gain during prolonged use in children.

Psychiatric disorders

Very rare: hyperactivity, toxic psychosis (sometimes with visual and tactile hallucinations), transient depressed mood.

Nervous system disorders

Very common: nervousness, insomnia, irritability.
Common: headache, drowsiness, dizziness, dyskinesia.
Very rare: convulsions, choreoathetoid movements, tics or exacerbation of existing tics and Tourette's syndrome, cerebrovascular disorders including vasculitis, cerebral haemorrhages and cerebrovascular accidents, reports of poorly documented neuroleptic malignant syndrome.

Eye disorders

Rare: difficulties in visual accommodation, blurred vision.

Cardiac disorders

Common: tachycardia, palpitation, arrhythmia, changes in blood pressure and heart rate (usually an increase).
Rare: angina pectoris.

Gastrointestinal disorders

Common: decreased appetite, abdominal pain, nausea and vomiting (which maybe alleviated by concomitant food intake), dry mouth.

Hepatobiliary disorders

Very rare: abnormal liver function, ranging from transaminase elevation to hepatic coma.

Skin and subcutaneous tissue disorders

Common: rash, pruritus, urticaria, fever, scalp hair loss.
Very rare: thrombocytopenic purpura, exfoliative dermatitis, erythema multiforme.

Musculoskeletal and connective tissue disorders

Common: arthralgia.
Very rare: muscle cramps.

General disorders and administration site conditions

Rare: slight growth retardation during prolonged use in children.

Adverse events reported since market introduction in patients taking methylphenidate include suicide, suicide attempt and suicidal ideation. No causal relationship between methylphenidate and these events has been established.

Dosage and Administration

Treatment should only be initiated by specialist doctors with experience in the use of the drug.

The dosage should be individualised according to the patient's clinical needs and responses.

Treatment with Attenta should be initiated at a low dose, with increments at weekly intervals. Daily dosage should not exceed 60 mg. In the treatment of ADHD, an attempt should be made to time administration of the drug to coincide with periods of greatest academic, behavioural or social difficulties for the patient.

If symptoms do not improve after dose titration over a one-month period, the drug should be discontinued.

Attenta should be discontinued periodically (e.g. over weekends, school holidays and long vacation) to assess the child's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued. Drug treatment should not, and need not, be indefinite and usually may be discontinued during or after puberty.

If therapy is interrupted for reasons other than those stated above, it should not be restarted at the dose that had been reached prior to treatment interruption, but should be re-titrated.

The rate of absorption, and therefore onset of action, is faster when the drug is taken with food. Dosage should therefore be standardised in relation to food to ensure consistency of effect.

Doses should be administered 1 to 2 hours before the maximum effect is required.

Children 6 years and Over
Start with 5 mg once or twice daily (e.g. at breakfast and at lunch) with gradual increments of 5 or 10 mg weekly. The total daily dosage should be administered in divided doses.

In some children with ADHD, sleeplessness may occur as the effect of the drug wears off. On rare occasions, an additional dose at about 8 pm may help; a trial dose may help to clarify the issue in an individual case, if the symptom warrants treatment.

Adults
Administer the tablets in divided doses two or three times daily. The average dose is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. Patients who are unable to sleep if Attenta is taken late in the day should take the last dose before 6 pm.

Dosing for each patient requires titration to control symptoms. Single doses greater than 20 mg are associated with sympathomimetic side effects. Therefore, the average single dose should be less than 20 mg. A maximum total dose of 60 mg/day may be required.

Overdosage

Symptoms
Signs and symptoms of acute overdosage, resulting principally from over-stimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitation, cardiac arrhythmias, hypertension, mydriasis and dryness of mucous membranes.

Treatment
Treatment consists of appropriate supportive measures and symptomatic treatment of life-threatening events, e.g. hypertensive crisis, cardiac arrhythmias, convulsions. The patient must be protected against self-injury and against external stimuli that would aggravate over-stimulation already present. If the signs and symptoms are not too severe and the patient is conscious, further absorption may be limited by administration of activated charcoal. In cases of marked agitation, intravenous doses of diazepam or haloperidol should be given. Hypertension may be controlled by alpha-adrenergic blocking agents or intravenous sodium nitroprusside. Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia.
Efficacy of peritoneal dialysis or extracorporeal haemodialysis for overdosage of methylphenidate has not been established.

Contact the Poisons Information Centre on 13 11 26 for advice on the management of overdosage.

Presentation and Storage Conditions

Attenta	Methylphenidate hydrochloride 10 mg tablet: white, round, scored, marked "MP" on one side, "α" on the other; blister packs of 100 tablets. 10

Poison Schedule of the Medicine

S8 (Controlled Drug)

Name and Address of the Sponsor

Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037

www.alphapharm.com.au

Date of Approval

Approved by the Therapeutic Goods Administration on 26 October 2004.
Date of most recent amendment: 19 March 2009.