

Package leaflet: Information for the user

Metylfenidat Amdipharm 10 mg modified-release hard capsules
Metylfenidat Amdipharm 20 mg modified-release hard capsules
Metylfenidat Amdipharm 30 mg modified-release hard capsules
Metylfenidat Amdipharm 40 mg modified-release hard capsules

methylphenidate hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What (Invented name) is and what it is used for
2. What you need to know before you or your child take (Invented name)
3. How to take (Invented name)
4. Possible side effects
5. How to store (Invented name)
6. Contents of the pack and other information

1. What (Invented name) is and what it is used for

What it is and what it is used for

(Invented name) is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD). It contains the active substance methylphenidate.

- It is used in children and adolescents between the ages of 6 and 18 years.
- It is used only after treatments which do not involve medicine, such as counselling and behavioural therapy, have been insufficient.

(Invented name) improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention span and concentration, and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes psychological, educational and social therapy.

Using treatment programmes as well as medicine helps to manage ADHD.

Treatment must only be initiated by, and used under the supervision of a doctor specialised in the treatment of ADHD, such as an expert paediatrician or a child and adolescent psychiatrist. Careful examination and monitoring during treatment by a specialist doctor is required.

About ADHD

Children and adolescents with ADHD find it hard to:

- sit still
- concentrate

It is not their fault that they cannot do these things.

Many children and adolescents struggle to do these things. However ADHD can cause problems with everyday life. Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places.

ADHD does not affect intelligence.

2. What you need to know before you or your child take (Invented name)

Do not take (Invented name) if you or your child:

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6).
- have a thyroid problem
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- have an eating problem where you do not feel hungry or want to eat (such as anorexia nervosa)
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- have ever had heart problems such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or an inherent heart problem
- have had a problem with the blood vessels in your brain such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- is currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) – see other medicines and (Invented name)
- have mental health problems such as:
 - a psychopathic or borderline personality problem
 - abnormal thoughts or hallucinations, or an illness called schizophrenia
 - signs of a severe mood problem like:
 - suicidal thoughts
 - severe depression, where you feel very sad, worthless and hopeless
 - mania, where you feel unusually excitable, over-active, and uninhibited

Do not take methylphenidate if any of the above applies to you or your child. If you are not sure, talk to your doctor or pharmacist before taking methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

Talk to your doctor or pharmacist before taking (Invented name) if you or your child:

- have liver or kidney problems
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEG)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs
- are female and have started having periods (see section ‘Pregnancy and breast-feeding below)
- have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words (tics)
- have high blood pressure
- have a heart problem which is not mentioned in the section “Do not take (Invented name) ”
- have a mental health problem which is not mentioned in the section “Do not take (Invented name) ”. Other mental health problems include:
 - mood swings (from being manic to being depressed, - known as bipolar disorder)
 - aggressive or hostile behaviour, or aggression which gets worse
 - seeing, hearing or feeling things that are not there (hallucinations)
 - believing things that are not true (delusions)
 - feeling unusually suspicious (paranoia)
 - feeling agitated, anxious or tense

- feeling depressed or guilty
- develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of (Invented name)

Tell your doctor or pharmacist if any of the above applies to you or your child before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

Checks that your doctor will make before you or your child start taking methylphenidate

These checks are to decide if methylphenidate is the correct medicine for you or your child. Your doctor will talk to you about:

- any other medicines you or your child are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you or your child are feeling, such as feeling high or low, having strange thoughts, or if you or your child have had any of these feelings in the past
- whether there is a family history of 'tics' (hard-to-control, repeated twitching of any parts of the body, or repeating sounds and words)
- any mental health or behaviour problems you, your child or other family members have or have ever had. Your doctor will discuss whether you or your child are at risk of having mood swings (from being manic to being depressed, - known as bipolar disorder). Your doctor will check your or your child's mental health history, and check if any of your family has a history of suicide, bipolar disorder or depression

It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you or your child. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Having an operation

Tell your doctor if you or your child are going to have an operation. Methylphenidate should not be taken on the day of your surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

Prolonged erections

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your or your child's erection lasts for longer than 2 hours, particularly if this is painful.

Drug testing

This medicine may give a positive result when testing for drug use.

Children and adolescents

Methylphenidate XL is not for use as a treatment for ADHD in children under 6 years of age. It is not known if it is safe or of benefit in children under 6 years of age.

Adults and elderly

(Invented name) is not for use as a treatment for ADHD in adults and the elderly above the age of 18 years. It is not known if it is safe or of benefit in adults and elderly.

Other medicines and (Invented name)

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Do not take methylphenidate if you or your child:

- are taking a medicine called a monoamine oxidase inhibitor (MAOI) used for depression, or have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in blood pressure

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you or your child are taking any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:

- other medicines for depression
- medicines for severe mental health problems
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain substances that can affect blood pressure. It is important to check with your pharmacist when you buy any of these medicines
- medicines that thin the blood to prevent blood clots

If you are in any doubt about whether medicines you or your child are taking are included in the list above, ask your doctor or pharmacist for advice before taking methylphenidate.

Methylphenidate with alcohol

Do not drink alcohol whilst taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Available data does not suggest an increased risk of overall birth defects, whilst a small increase in the risk of heart malformations when used during the first three months of pregnancy could not be ruled out. Your doctor will be able to give you more information about this risk. Tell your doctor or pharmacist before using methylphenidate if you or your daughter is:

- having sex. Your doctor will discuss contraception
- pregnant or might be pregnant. Your doctor will decide whether methylphenidate should be taken
- breast-feeding or are planning to breast-feed. It is possible that methylphenidate is passed into breast milk, so your doctor will decide whether you or your daughter should breast-feed while taking methylphenidate

Driving and using machines

You or your child may feel dizzy, have problems focusing or have blurred vision when taking methylphenidate. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How to take (Invented name)

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- (Invented name) is a modified release form of methylphenidate which releases the medicine gradually over a time period of 8 hours. It is intended to take the place of the same total daily dose of traditional (immediate release) methylphenidate taken at breakfast and lunchtime.
- If you or your child have not taken methylphenidate before, your doctor will normally start treatment with traditional (immediate release) methylphenidate tablets. If your doctor feels it is necessary methylphenidate treatment may be started with (Invented name) 10 mg once daily before breakfast
- Your doctor will usually start treatment with a low dose and increase it gradually as required
- The maximum daily dose is 60 mg

How to take

(Invented name) is for oral use. It should be given in the morning before breakfast. The capsules may be swallowed whole with a drink of water, or alternatively, may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of soft food (e.g. applesauce) and taken immediately, and not stored for future use. If the medicine is taken with soft food some fluid, e.g. water, should be taken afterwards. The capsules and the capsule contents must not be crushed or chewed.

Long-term treatment

(Invented name) does not need to be taken for ever. If you or your child takes (Invented name) for more than a year, your doctor will stop treatment for a short time, e.g. during a school holiday. This will show if the medicine is still needed.

If you do not feel better after 1 month of treatment

If you or your child do not feel better, tell your doctor. They may decide you need a different treatment.

Not using (Invented name) properly

If (Invented name) is not used properly, this may cause abnormal behaviour. It may also mean that you or your child start to depend on the medicine. Tell your doctor if you or your child have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Things your doctor will do during treatment

Your doctor will do some tests

- before you or your child start treatment, to make sure that (Invented name) is safe and will be of benefit
- after you or your child has started treatment, at least every 6 months, but possibly more often. They will also be done when the dose is changed
- these tests will include:
 - checking your appetite
 - measuring height and weight
 - measuring blood pressure and heart rate
 - checking whether you have any problems with your mood, state of mind or any other unusual feelings, or if these have got worse while taking (Invented name) .

If you or your child take more (Invented name) than you should

If you or your child take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken.

Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations or psychosis), sweating, flushing, headache, high fever, changes in heartbeat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you or your child forget to take (Invented name)

Do not take a double dose to make up for a forgotten dose. If you or your child forget a dose, wait until it is time for the next dose.

If you or your child stop taking (Invented name)

If you or your child suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping (Invented name) .

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Although some people get side effects, most people find that methylphenidate helps them. Your doctor will talk to you about these side effects.

Some side effects could be serious. If you or your child have any of the side effects below, see a doctor straight away:

Common (may affect up to 1 in 10 people)

- uneven heartbeat (palpitations)
- mood changes, mood swings or changes in personality

Uncommon (may affect up to 1 in 100 people)

- thinking about or feeling like killing yourself
- seeing, feeling, or hearing things that are not real - these are signs of psychosis
- uncontrolled speech and body movements (Tourette's)
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

Rare (may affect up to 1 in 1,000 people)

- feeling unusually excited, over-active and uninhibited (mania)

Very rare (may affect up to 1 in 10,000 people)

- heart attack
- fits (seizures, convulsions, epilepsy)
- skin peeling or purplish red patches
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system - due to a temporary lack of blood supply to the brain
- paralysis or problems with movement and vision, difficulties in speech - these can be signs of problems with the blood vessels in your brain
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other medicines that may be taken in combination with methylphenidate

Not known (frequency cannot be estimated from the available data)

- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath - these can be signs of heart problems

If you have any of the side effects above, see a doctor straight away.

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

Very common (may affect more than 1 in 10 people)

- headache
- feeling nervous
- not being able to sleep

Common (may affect up to 1 in 10 people)

- joint pain
- dry mouth
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite or decreased appetite
- itching, rash or raised red itchy rash (hives)
- cough, sore throat or nose and throat irritation
- high blood pressure, fast heart beat (tachycardia)
- feeling dizzy, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable and behaving abnormally
- excessive teeth grinding (bruxism)

Uncommon (may affect up to 1 in 100 people)

- constipation
- chest discomfort
- blood in the urine
- double vision or blurred vision
- muscle pain, muscle twitching
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, excessive awareness of surroundings, problems sleeping
- tremor
- dry eye

Rare (may affect up to 1 in 1,000 people)

- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men
- excessive sweating, redness of the skin, raised red skin rash
- Obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

Very rare (may affect up to 1 in 10,000 people)

- sudden death
- muscle cramps
- small red marks on the skin
- inflammation or blocked arteries in the brain
- abnormal liver function including liver failure and coma
- changes in test results including liver and blood tests
- suicidal attempt, suicide, abnormal thinking, lack of feeling or emotion,
- fingers and toes feeling numb, tingling and changing colour from white to blue, then red when cold (Raynaud's phenomenon)

Not known (frequency cannot be estimated from the available data)

- migraine
- excessive talkativeness

- very high fever
- slow, fast or extra heart beats
- a major fit (grand mal convulsions)
- believing things that are not true, confusion
- severe stomach pain, often with feeling and being sick
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- inability to control urination (incontinence)
- prolonged erections, sometimes painful, or an increased number of erections, inability to develop or maintain an erection
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- nosebleed
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

Effects on growth

When used for more than one year, methylphenidate may cause reduced growth in some children. This affects less than 1 in 10 children.

- There may be lack of weight gain or height increase.
- Your doctor will carefully monitor you or your child's height and weight, as well as how well you or your child are eating.
- If you or your child are not growing as expected, then treatment with methylphenidate may be stopped for a short time.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store (Invented name)

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the bottle tightly closed in order to protect from moisture.

Do not use this medicine if the capsules look damaged in any way.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What (Invented name) contains

- The active substance is methylphenidate hydrochloride.
(Invented name) 10 mg modified-release hard capsules contain 10 mg methylphenidate hydrochloride equivalent to 8.65 mg methylphenidate.
(Invented name) 20 mg modified-release hard capsules contain 20 mg methylphenidate hydrochloride equivalent to 17.3 mg methylphenidate.
(Invented name) 30 mg modified-release hard capsules contain 30 mg methylphenidate hydrochloride equivalent to 25.95 mg methylphenidate.

(Invented name) 40 mg modified-release hard capsules contain 40 mg methylphenidate hydrochloride equivalent to 34.59 mg methylphenidate.

- The other excipients are:

Capsule contents: microcrystalline cellulose, hypromellose, ethylcellulose, hydroxypropylcellulose, dibutyl sebacate, povidone, talc(E553b), hydrochloric acid (E507-for pH adjustment)

Capsule shell: hypromellose, titanium dioxide (E171), iron oxide yellow (E172) (additionally in (Invented name) 20 mg, 30 mg, 40mg modified-release hard capsules) and iron oxide red (E172) (additionally in (Invented name) 40 mg modified-release hard capsules)

- *Printing ink:* shellac (E904), iron oxide black (E172), propylene glycol (E1520), potassium hydroxide (E525)

What (Invented name) looks like and contents of the pack

Modified-release hard capsule

(Invented name) 10 mg modified-release hard capsules

Opaque oblong hard capsule with white cap and white body imprinted “10” with black ink on body filled with white to off-white spherical pellets. Capsule length: 16 mm.

(Invented name) 20 mg modified-release hard capsules

Opaque oblong hard capsule with ivory cap and white body imprinted “20” with black ink on body filled with white to off-white spherical pellets. Capsule length: 16 mm.

(Invented name) 30 mg modified-release hard capsules

Opaque oblong hard capsule with yellow cap and white body imprinted “30” with black ink on body filled with white to off-white spherical pellets. Capsule length: 18 mm.

(Invented name) 40 mg modified-release hard capsules

Opaque oblong hard capsule with light orange cap and white body imprinted “40” with black ink on body filled with white to off-white spherical pellets. Capsule length: 19 mm.

(Invented name) 10 mg/20 mg/30 mg/40 mg modified-release hard capsules are available in:

HDPE bottles with child-resistant PP screw caps containing a desiccant

Pack sizes:

For 10 mg, 20 mg and 30 mg - 28, 30, 50, 60, 100 modified-release hard capsules

For 40 mg - 28, 30, 40, 60 modified-release hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

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