Package leaflet: information for the patient

Methylphenidate hydrochloride 5 mg Tablets
Methylphenidate hydrochloride 10 mg Tablets

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

1. WHAT METHYLPHENIDATE HYDROCHLORIDE IS AND WHAT IT IS USED FOR

Methylphenidate Hydrochloride contains the active substance methylphenidate.

Methylphenidate Hydrochloride is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).
- It is used in children and young people between the ages of 6 and 18.
- It is used only after trying treatments which do not involve medicines. Such as counselling and behavioural therapy.

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

How it works

Methylphenidate Hydrochloride improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour. The medicine is given as part of a treatment programme, which usually includes:
- psychological
- educational and
- social therapy.

Methylphenidate Hydrochloride must only be initiated by, and used under the supervision of, a specialist in childhood/ and or adolescent behavioural disorders. Although there is no cure for ADHD, it can be managed using treatment programmes.

About ADHD

Children and young people with ADHD find it hard:
- to sit still and
- to concentrate.

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

Many children and young people struggle to do these things. However, with ADHD they 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 the intelligence of a child or young person.

2. WHAT YOU NEED TO KNOW BEFORE YOU OR YOUR CHILD TAKES METHYLPHENIDATE

Do not take methylphenidate 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 when 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 were born with a 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)
- have mental health problems such as:
  - a 'psychopathic' or 'borderline personality' problem
  - abnormal thoughts or visions or an illness called 'schizophrenia'
  - signs of a severe mood problem like:
    - feeling like killing yourself
    - severe depression, where you feel very sad, worthless and hopeless
    - mania, where you feel unusually excitable, over-active, and un-inhibited.

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

Check with your doctor or pharmacist before taking Methylphenidate Hydrochloride if you or your child:
- 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 erection lasts for longer than 2 hours, particularly if this is painful.
- you have liver or kidney problems
- you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- you have ever abused or been dependent on alcohol, prescription medicines or street drugs
- you are a girl and have started your periods (see the 'Pregnancy, breast-feeding and contraception' section below)
- you have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- you have high blood pressure
- you have a heart problem which is not in the 'Do not take' section above
- develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Methylphenidate Hydrochloride
- you have a mental health problem which is not in the 'Do not take' section above. Other mental health problems include:
  - mood swings (from being manic to being depressed - called 'bipolar disorder')
  - starting to be aggressive or hostile, or your aggression 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.

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 Hydrochloride

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, your child 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 or 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 - called '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 or your child start taking this medicine.

Other medicines and Methylphenidate Hydrochloride

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 Hydrochloride 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 your 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 medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots

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

Having an operation

Tell your doctor if you are going to have an operation. You should not take methylphenidate 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 and heart rate during the operation.

Drug testing/anti-doping testing

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

Methylphenidate Hydrochloride with food and alcohol

Taking methylphenidate with food may help relieve stomach pains, feeling sick or vomiting. Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy, breast-feeding and fertility

Available data do not suggest an increased risk of overall birth defects, whilst a small increase in the risk of malformations of the heart 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. Methylphenidate is present in breast milk. Tell your doctor or pharmacist before using methylphenidate if you or your daughter:
- are sexually active. Your doctor will discuss contraception
- are pregnant or might be pregnant. Your doctor will decide whether methylphenidate should be taken
- are breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk. Therefore, your doctor will decide whether you or your daughter should breast-feed while taking methylphenidate.

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.

Driving or using machines

You may feel dizzy, have problems focussing 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.

Methylphenidate Hydrochloride contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE METHYLPHENIDATE HYDROCHLORIDE

How much to take

Always take Methylphenidate Hydrochloride exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- your doctor will usually start treatment with a low dose and increase it gradually as required.
- the maximum daily dose is 60 mg.
- take Methylphenidate Hydrochloride once or twice daily (e.g. at breakfast or/and lunchtime).
- the tablets should be swallowed with a drink of water.
- you can break the tablets to make it easier to swallow.

If you or your child do not feel better after 1 month of treatment

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

Not using Methylphenidate Hydrochloride properly

If Methylphenidate Hydrochloride is not used properly, this may cause abnormal behaviour. It may also mean that you or your child starts to depend on the medicine. Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or street drugs.

This medicine is only for you or your child. Do not give this medicine to anyone else, even if their symptoms seem similar.

If you or your child take more Methylphenidate Hydrochloride than you or your child should

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

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), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils, dry nose and mouth, muscle spasms, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you or your child forget to take Methylphenidate Hydrochloride

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

If you or your child stop taking Methylphenidate Hydrochloride

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 Methylphenidate Hydrochloride.

Things your doctor will do when you or your child are on treatment

Your doctor will do some tests
- before you start - to make sure that Methylphenidate Hydrochloride is safe and will be of benefit.
- after you start - they will be done 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 Methylphenidate Hydrochloride.

Long-term treatment

Methylphenidate Hydrochloride does not need to be taken for ever. If you take Methylphenidate Hydrochloride for more than a year, your doctor should stop treatment for a short time, this may happen during a school holiday. This will show if the medicine is still needed.

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, go immediately to the nearest hospital emergency department:

Common (may affect up to 1 in 10 people):
- uneven heartbeat (palpitations)
- mood changes or mood swings or changes in personality
- excessive teeth grinding (bruxism)

Uncommon (may affect up to 1 in 100 people):
- thinking about or feeling like killing yourself
- feeling, or hearing things that are not real, these are signs of psychosis
- uncontrolled speech and body movements (Tourette's)

continued overleaf

- 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 un-inhibited (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 drugs 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)
- prolonged erections, sometimes painful, or an increased number of erections

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
- decreased weight
- itching, rash or raised red itchy rashes (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 abnormal behaviour
- stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick. These usually occur at the beginning of treatment and may be reduced by taking the medicine with food.

Uncommon (may affect up to 1 in 100 people):
- constipation
- chest discomfort
- blood in the urine
- shaking and trembling
- double vision or blurred vision
- muscle pain, muscle twitching
- shortness of breath or chest pain
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, excessive awareness of surroundings, problems sleeping
- 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, red raised 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):
- heart attack
- 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, 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
- 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
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- erectile dysfunction
- excessive uncontrolled talking
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering
- 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 a 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 growth.
- Your doctor will carefully watch your child height and weight, as well as how well your child is eating.
- If your child is 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 Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE METHYLPHENIDATE HYDROCHLORIDE

- 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 and the tablet blister foil after 'EXP.' The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage condition.

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 Methylphenidate Hydrochloride contains

Methylphenidate Hydrochloride 5 mg tablets

The active substance is methylphenidate hydrochloride. Each tablet contains 5 mg methylphenidate hydrochloride.

Methylphenidate Hydrochloride 10 mg tablets

The active substance is methylphenidate hydrochloride. Each tablet contains 10 mg methylphenidate hydrochloride.

The other ingredients are: lactose monohydrate, maize starch, sodium starch glycolate type A, hypromellose, citric acid monohydrate, silica, coloidal anhydrous and magnesium stearate.

What Methylphenidate Hydrochloride looks like and contents of the pack

Methylphenidate Hydrochloride 5 mg tablets are white to off white, circular, flat bevelled edged tablets of approximately 5.5 mm diameter, engraved with '5' on one side and '73' on the other side

Methylphenidate Hydrochloride 10 mg tablets are white to off-white, circular, flat bevelled edged tablets of approximately 7 mm diameter with a breakline, engraved "10" on one side and "73" on the other side.

Methylphenidate Hydrochloride 5 mg and 10 mg tablets are available in packs containing 30 tablets.

Marketing Authorisation Holder

Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL, United Kingdom

Manufacturer

Tillomed Laboratories Limited
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Other formats

To request a copy of this leaflet in Braille, large print or audio, please call 0800 970 6115.

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Information for children and young people with ADHD

This info is to help you learn the main things about your medicine called Methylphenidate Hydrochloride.
If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.
It may help if you read small bits at a time.

Why have I been given this medicine?

This medicine can help children and young people with 'ADHD'.
- ADHD can make you:
  - run about too much
  - not be able to pay attention
  - act quickly without thinking about what will happen next (impulsive).
- It affects learning, making friends and how you think about yourself. It is not your fault.

While you are taking this medicine
- As well as taking this medicine you will also get help with ways to cope with your ADHD such as talking to ADHD specialists.
- This medicine should help you. But it does not cure ADHD.
- You will need to go to your doctor several times a year for check ups. This is to make sure the medicine is working and that you are growing and developing OK.
- If you take the medicine for more than one year, your doctor may stop your medicine to see if it is still needed. This will probably happen in a school holiday.
- If you take this medicine more than once a day, you may have to remember to take it **at school or college**. You or your mum, dad or carer will need to find out what the school rules are about this.
- Do not drink alcohol. Alcohol may make the side effects of this medicine worse.
- Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies. If you are having sex, please talk to your doctor about contraception.

Some people cannot have this medicine

You cannot have this medicine if:
- you have a problem with your heart
- you feel very unhappy, depressed or have a mental illness.

Some people need to talk to their doctor before they start having this medicine

You need to talk to your doctor if:
- you have epilepsy (fits)
- you are pregnant or breastfeeding
- you are taking other medicines – your doctor needs to know about all the medicines you are taking.

How do I take my medicine (tablets)?
- Swallow your medicine with water.
- Your doctor will tell you how many times a day you should take your medicine
- Do not stop taking the medicine without talking to your doctor first.

Possible side effects

Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen or if you have any concerns about other possible side effects tell an adult you trust straight away. They can then talk to your doctor. The main things that could affect you are:
- Feeling or being sick, having tummy pains or having a dry mouth. These may only happen when you first start taking the medicine. It is best to take the medicine with food
- Feeling worried or nervous
- Feeling shaky, trembling or being unusually active
- Feeling dizzy, or getting head aches
- Being very depressed and unhappy or wanting to hurt yourself
- Being very sweaty
- Having different moods than usual, not being able to get to sleep
- Skin rashes, bruising easily, getting out of breath or chest pains
- The medicine can also make you feel **sleepy**. If you feel sleepy, it is important **not to do outdoor sports** like riding a horse or bike, swimming or climbing trees. You could hurt yourself and others.
- Your heart beating faster than usual.

If you feel unwell in any way while you are taking your medicine please tell an adult you trust straight away.

Other things to remember
- Make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.
- The medicine is special for you - **do not let anyone else have it**. It may help you, but it could hurt someone else.
- If you forget to take your medicine **don't** take two tablets the next time. Just take one tablet at the next normal time.
- If you do take too much medicine, tell your mum, dad or carer **right away**.
- It is important not to take too much medicine or you will get ill.
- Don't stop taking your medicine until your doctor says it's OK.

Who should I ask if there is anything I don't understand?

Your mum, dad, carer, doctor, nurse or pharmacist will be able to help you.

Product Name	Methylphenidate HCl Tabs	**Sap code :**	TBA	**Reference Artwork**	TW225983 (SmPC)
Packaging Material	Package leaflet	**Reason of change :**	TW228349 (rel)	Proof 1	03/11/2025
Size : Foil Width		**Country :**	UK	Proof 2	03/11/2025
Size : Foil Repeat Length		**Pack Size :**	All	Proof 3	26/11/2025
Size : Strip Size		**Barcode No. :**	NA	Proof 4	04/12/2025
Size : PI - Open Size	320 mm (w) x 450 mm (l)	**Pharmacode :**	TBA	Proof 5	10/12/2025
Size : Carton/Label		**No. of colours :**	1		
PM Style/Type :		**Min. Font Size :**	9 points (Reg text)		
Remark (If any) :					

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