PACKAGE LEAFLET

Package leaflet: Information for the user

Methylphenidate Hydrochloride 2mg/ml oral solution

Methylphenidate hydrochloride

The name of your medicine is Methylphenidate Hydrochloride. It contains the active substance 'methylphenidate hydrochloride'. The name 'methylphenidate' will be used in this leaflet.

Important things you need to know about your medicine

This medicine is used to treat ADHD
- The full name for ADHD is 'Attention Deficit Hyperactivity Disorder'.
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other treatments for ADHD as well as this medicine.

Read Section 1 for more information**.**

Before you take this medicine, talk to your doctor if:
- You have heart, circulation, or mental health problems – you may not be able to take this medicine.
- You are taking any other medicines – this is because methylphenidate can affect how other medicines work.

Read Section 2 for more information.

While taking this medicine:
- See your doctor regularly. This is because your doctor will want to check how the medicine is working.
- Do not stop taking the medicine without first talking to your doctor.
- Your doctor may stop your medicine to see if it is still needed, if you take it for more than a year.
- The most common side effects are feeling nervous, not being able to sleep or having a headache.

Read Sections 3 and 4 for more information.

Talk to your doctor straight away if any of the following happen:
- Your mood and how you feel changes.
- You feel any problems with your heart.

Read Section 4 for more information.

The rest of this leaflet includes more detail and other important information on the safe and effective use of this medicine.
- 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. Do not pass it on to others. It may harm them, even

if their symptoms are the same as yours.
- If any of the side effects worry you, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

This leaflet has been written in sections:
- Sections 1 to 6 are for parents and carers (sometimes called 'your guardians').
- The last section is a special section for a child or young person to read.

However, all sections are written as though the child or young person taking the medicine is reading them.
The sections are:
1. What Methylphenidate is and what it is used for
2. What you need to know before you take methylphenidate
3. How to take methylphenidate
4. Possible side effects
5. How to store methylphenidate
6. Contents of the pack and other information

Information for children and young people
Now read the rest of this leaflet before you start taking this medicine.

1. What Methylphenidate is and what it is used for

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

Methylphenidate 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 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 behavior.
The medicine is given as part of a treatment program, which usually includes:
- psychological
- educational and
- social therapy.

It is prescribed only by doctors who have experience in children or young people's behavior problems. Although there is no cure for ADHD , it can be managed using treatment programs.

About ADHD
Children and young people with ADHD find it:
- hard to sit still and
- hard 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. Before you take methylphenidate

Do not take methylphenidate if:

- you are allergic to methylphenidate or any of the other ingredients of this medicine (listed in Section 6)
- you have a thyroid problem
- you have increased pressure in your eye (glaucoma)
- you have a tumour of your adrenal gland (phaeochromocytoma)
- you have an eating problem when you do not feel hungry or want to eat – such as 'anorexia nervosa'
- you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- you 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
- you 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)
- you 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 if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take methylphenidate. This is because methylphenidate can make these problems worse.

Check with your doctor or pharmacist before treatment if:

- 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
- you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Methylphenidate.
- 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 apply to you before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you.

Checks that your doctor will make before you start taking methylphenidate
These checks are to decide if methylphenidate is the correct medicine for you. Your doctor will talk to you about:

- any other medicines you 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 are feeling, such as feeling high or low, having strange thoughts or if you 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 behavior problems you or other family members have ever had. Your doctor will discuss whether you are at risk of having mood swings (from being manic to being depressed -called 'bipolar disorder'). They will check your mental health history, and check if any of your family have 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. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Other medicines and methylphenidate
Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take methylphenidate if you:

- 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 are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you 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 are taking are included in the list above, ask your doctor or pharmacist 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 anesthetic is used. This is because there is a chance of a sudden rise in blood pressure and heart rate during the operation.

Drug testing

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

Taking methylphenidate with food and drink

Taking methylphenidate with food may help to stop stomach pains, feeling sick or being sick.

Taking methylphenidate with alcohol

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. No effects on fertility have been seen in animals. Tell your doctor or pharmacist before using methylphenidate if you (or your daughter) are:

- having sex. Your doctor will discuss contraception with you.
- pregnant or think you may be pregnant. Your doctor will decide whether you should take methylphenidate.
- 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 should breast-feed while taking methylphenidate.

Driving or using machines

You 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.

Important information about some of the ingredients of Methylphenidate 2mg/ml oral solution

Sorbitol:
This medicine contains 175 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may also cause gastrointestinal discomfort and mild laxative effect.

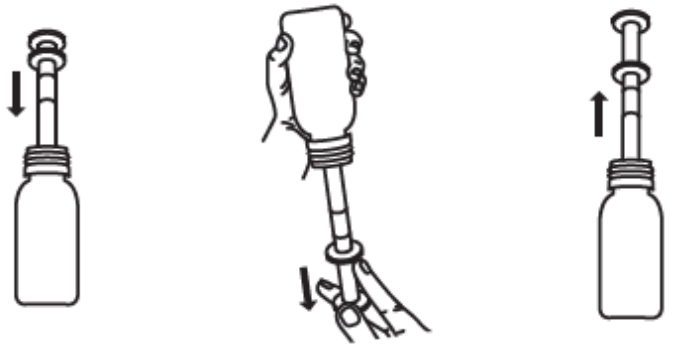
Propylene glycol:
This medicine contains 90 mg propylene glycol in each ml. If you (or your child) suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. If you (or your daughter) are pregnant or breast feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Sodium benzoate:
This medicine contains 1 mg sodium benzoate in each ml.

Sodium:
This medicine contains less than 1 mmol sodium (23mg) per ml, that is to say essentially 'sodium-free'

3. How to take Methylphenidate

- Shake the bottle for at least 10 seconds and remove the cap.
- There is a plug with a hole in the neck of the bottle. Insert the end of the syringe into the hole and ensure it is secure.
- Hold the syringe in place and turn the bottle upside down and gently pull down the plunger to requested dose.
- Turn the bottle the right way up.
- Remove the syringe by holding onto the bottle and twisting out gently.
- Place the syringe inside your mouth against the cheek and press the plunger slowly to gently release the medicine.
- After use, the plug should remain in the neck of the bottle. Wipe the plug and neck clean and rinse the cap before replacing.
- The syringe should be washed and dried after use. It should be cleaned by hand without removing the plunge.



How much to take
Always take Methylphenidate exactly as your doctor or pharmacist 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 60mg (30ml).
- take methylphenidate once or twice daily (e.g. at breakfast or/and lunchtime).
- the oral solution should be swallowed with a drink of water.

If you do not feel better after 1 month of treatment.
If you do not feel better, tell your doctor. They may decide you need a different treatment.

Not using Methylphenidate properly
If Methylphenidate is not used properly, this may cause abnormal behavior. It may also mean that you start to depend on the medicine. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
This medicine is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

If you take more Methylphenidate than you should
If you 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), 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 forget to take methylphenidate
Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

If you stop taking methylphenidate

If you suddenly stop taking this medicine, 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.

Things your doctor will do when you are on treatment

Your doctor will do some tests

- before you start – to make sure that methylphenidate 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.

Long-term treatment

Methylphenidate does not need to be taken for ever. If you take methylphenidate 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 product, ask your doctor or pharmacist.

4. Possible Side effects

Like all medicines, methylphenidate can cause side effects, but 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 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 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)
- 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.

Other side effects (how often they happen is not known)
- 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 behavior
- 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, skinpicking, 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 color (from white to blue, then red) when cold ('Raynaud's phenomenon')

Other side effects (how often they happen is not known):
- 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 height and weight, as well as how well you are eating.
- If you are not growing as expected, then your treatment with methylphenidate may be stopped for a short time.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Methylphenidate

- Keep out of the sight and reach of children
- Make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.
- Do not use methylphenidate after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- Do not use methylphenidate after the bottle has been opened for more than a month.
- Store below 25ºC

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 contains
The active substance is methylphenidate hydrochloride.
Each 1 ml of Methylphenidate Hydrochloride oral solution contains 2 mg of the active substance, methylphenidate hydrochloride.

The other ingredients are: propylene glycol (E 1520), glycerol (E 422), macrogol 1500, sodium benzoate (E 211), liquid sorbitol (E420), hydrochloric acid (to adjust pH) and purified water.

What methylphenidate looks like and contents of the pack
Methylphenidate Hydrochloride oral solution is a clear, colorless solution. It is packed in a 150 ml amber glass bottle with a plastic child-resistant and tamper evident cap. It contains a 5ml oral syringe with 0.25ml graduations.
Where higher doses are to be administered, dosing cups should be considered.

Marketing Authorisation Holder
Consilient Health Ltd.
Floor 3, Block 3,
Miesian Plaza,
Dublin 2,
D02Y754,
Ireland.

Manufacturer
Labomed Pharmaceutical Company S.A.
84 Ioannou Metaxa str.
Koropi, Attica, 19441
Greece

Other sources of information
To request a copy of this leaflet in braille, large print or audio please email drugsafety@consilienthealth.com.

This leaflet was last revised in September 2025.

Information for children and young people with ADHD

This info is to help you learn the main things about your medicine called methylphenidate.
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 checkups. 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 (oral solution)?

- 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 double dose the next time. Just take one dose 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.