

Package Leaflet: Information for the user**Ritalin® 10mg tablets**

(methylphenidate hydrochloride)

The name of your medicine is Ritalin 10mg tablets but will be referred to as Ritalin throughout the remainder of this leaflet.

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. Do not pass it on to others. It may harm them, even if their symptoms 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 Ritalin is and what it is used for
2. What you need to know before you take Ritalin
3. How to take Ritalin
4. Possible side effects
5. How to store Ritalin
6. Contents of the pack and other information

Information for children and young people with ADHD**1. What Ritalin is and what it is used for**

Ritalin contains the active substance 'methylphenidate hydrochloride'. It belongs to a group of medicines known as psychostimulants.

What it is used for

Ritalin is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).

- It is used in children and young people aged 6 years and over and in adults.
- It is used only after trying treatments which do not involve medicines, such as counselling and behavioural therapy and which have been insufficient.

Ritalin is not for use as a treatment for ADHD in children under 6 years of age or in patients older than 60 years. It is not known if it is safe or of benefit in these age groups.

How it works

Ritalin 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.

Ritalin 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, a child and adolescent psychiatrist or a psychiatrist. A thorough examination is necessary. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood. Using treatment programmes as well as medicine helps to manage ADHD.

Contact your doctor if you or your child do not feel any improvement or if you or your child feel worse.

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. Adults with ADHD often find it hard to concentrate. They often feel restless, impatient and inattentive. They may have difficulty organising their private life and work. ADHD does not affect intelligence. Not all patients with ADHD need to be treated with medicine and the decision to treat with Ritalin requires a very thorough assessment of the severity and duration of the patient's symptoms in relation to age.

Examinations during treatment with Ritalin

Your doctor will regularly check your (or your child's) health while being treated with Ritalin (please read carefully section 3, 'Things your doctor will do when you or your child are on treatment').

2. What you need to know before you take Ritalin**Do not take Ritalin if you or your child:**

- are allergic (hypersensitive) to methylphenidate or any of the other ingredients of this medicine (listed in Section 6)
- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days (see 'Other medicines and Ritalin')
- have a thyroid problem
- have increased pressure in the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- have an eating problem when not feeling hungry or wanting 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 the 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
 - severe (type 1) bipolar disorder (switch between depression and mania) that is not well controlled.

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

Warnings and precautions

Check with your doctor or pharmacist before taking Ritalin if you or your child:

- have liver or kidney problems
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- have ever abused or been dependent on alcohol, prescription medicines, or street drugs
- are female and have started your periods (see the 'Pregnancy and breast-feeding' section below)
- have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- have high blood pressure
- have a heart problem which is not in the 'Do not take' section above
- 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.

Information for children and young people with ADHD

This info is to help you learn the main things about your medicine called Ritalin.

If you don't enjoy reading, someone like your mum, dad, or carer/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 and doing homework, 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.

Tell your doctor or pharmacist if any of the above apply to you or your child before starting treatment.

This is because Ritalin can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Ritalin.

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

These checks are to decide if Ritalin 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 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 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'). They will check your or your child's 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 Ritalin 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.

If you or your child have or have had heart problems before starting treatment or develop heart symptoms during treatment with Ritalin, tell your doctor immediately, who will refer you to a heart specialist.

During treatment, boys and men 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 the erection lasts for longer than 2 hours, particularly if this is painful.

Other medicines and Ritalin

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

Do not take Ritalin 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 Ritalin may cause a sudden increase in blood pressure.

If you or your child are taking other medicines, Ritalin may affect how well they work or may cause side effects. It may therefore be necessary to adjust the dosage of the medicine or to stop taking it altogether. If you or your child are taking any of the following medicines, check with your doctor or pharmacist before taking Ritalin:

- other medicines for depression
- medicines for severe mental health problems (e.g. to treat schizophrenia)
- 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 before taking Ritalin.

Having an operation

Tell your doctor if you or your child are going to have an operation. Ritalin should not be taken on the day of 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

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

Ritalin with food, drink and alcohol

Ritalin may be taken with or without food. Taking this medicine with food may help to stop stomach pains, feeling sick or being sick. If you or your child notice a decrease in appetite while taking this medication, try to avoid taking it just before a meal. Instead, try taking it with food or after finishing eating. 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 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 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.

Tell your doctor or pharmacist before using Ritalin if you or your daughter are:

- having sex. Your doctor will discuss contraception with you or your daughter
- pregnant, think you may be pregnant, or are planning to become pregnant. Your doctor will decide whether you or your daughter should take Ritalin.
- 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 Ritalin.

Driving and using machines

You or your child may feel dizzy or drowsy, have problems focusing the eyes or have blurred vision, or have hallucinations or other central nervous system side effects when taking Ritalin. 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 Ritalin

Lactose:

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Wheat starch (containing gluten):

This medicine contains only very low levels of gluten (from wheat starch) and is very unlikely to cause problems if you have coeliac disease.

One Ritalin 10 mg tablet contains no more than 4.8 micrograms of gluten. If you or your child have wheat allergy (different from coeliac disease) you or your child should not take this medicine.

3. How to take Ritalin

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

How much to take

- Your doctor will usually start treatment with a low dose and increase it gradually as required. The last doses should, in general, not be given within 4 hours before bedtime in order to prevent disturbances in falling asleep.
- Children and adolescents: the maximum daily dose is 60 mg.
- Adults: the maximum daily dose is 80 mg.
- At the beginning of treatment, Ritalin is taken once or twice daily (e.g. at breakfast or/and lunchtime). As your treatment continues, your doctor may ask you to take it more often (e.g. 2-3 times daily).

How to take Ritalin

- Ritalin can be taken with or without food.
- The tablets should be swallowed with a drink of water.
- The tablets can be divided into equal doses.

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 you or your child need a different treatment.

- 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.
- you suffer from an eating disorder.

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 breast-feeding
- you are taking other medicines – your doctor needs to know about all the medicines you are taking.



Things your doctor will do when you are on treatment

Your doctor will do some tests and checks

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

Long-term treatment

Ritalin does not need to be taken forever. If you or your child take Ritalin for more than a year, your doctor should stop treatment at least once per year for a short time. For children and adolescents, this may happen during a school holiday. This will show if the medicine is still needed.

Not using Ritalin properly

Attention should be paid to the risk of diversion, misuse and abuse of this medicine. Long-term abuse of Ritalin XL may lead to a lack of efficacy of usual doses (tolerance), psychological dependence, abnormal behaviour or psychotic episodes (hallucinations, delusions). It may also mean that you or your child become dependent on the medicine. Tell your doctor if you or your child have 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 symptoms seem similar.

If you or your child take more Ritalin 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. You or your child may need medical treatment.

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 Ritalin

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

If you or your child stop taking Ritalin

If you or your child suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may occur. Talk to your doctor before stopping Ritalin.

If you have any further questions on the use of this product, 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 Ritalin 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 (affects less than 1 in 10 people)

- uneven/irregular heartbeat (palpitations, arrhythmia)
- changes in personality

Uncommon (affects less than 1 in 100 people)

- thinking about or feeling like killing yourself
- mood changes or mood swings
- feeling or hearing things that are not real (hallucinations), these are signs of psychosis
- uncontrolled speech and body movements (tics, Tourette's)
- heart murmur (detected by auscultation of the heart)
- 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 (affects less than 1 in 1,000 people)

- feeling unusually excited, over-active and un-inhibited (mania)

Very rare (affects less than 1 in 10,000 people)

- heart attack (with risk of sudden death)
- fits (seizures, convulsions)
- skin peeling or purplish red patches
- suicidal attempt (including completed suicide)
- 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
- inflammation or blocked arteries in the brain
- 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 Ritalin or other drugs that may be taken in combination with Ritalin.

Not known (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)
- problems with blood vessels in the brain (stroke, cerebral arteritis, or cerebral occlusion)
- a major fit ('grand mal convulsions')
- dependence on methylphenidate

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

Very common (affects more than 1 in 10 people)

- decreased appetite
- headache
- feeling nervous
- not being able to sleep
- feeling sick
- dry mouth

Common (affects less than 1 in 10 people)

- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite
- reduced weight gain and growth retardation during prolonged use in children
- weight loss in adults
- panic attack
- decrease in sex drive
- toothache
- itching, rash or raised red itchy rashes (hives)
- excessive sweating
- cough, sore throat or nose and throat irritation, shortness of breath
- changes in blood pressure (usually high blood pressure), fast heartbeat (tachycardia)
- cold hands and feet
- shaking or trembling, feeling dizzy, movements which you cannot control, feeling jittery, being unusually active

- feeling aggressive, agitated, restless, anxious, depressed, stressed, irritable and abnormal behaviour, problems sleeping, tiredness
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst, and being sick
- excessive teeth grinding (bruxism)

Uncommon (affects less than 1 in 100 people)

- constipation
- chest pain
- blood in the urine
- double vision or blurred vision
- muscle pain, muscle twitching, muscle tightness
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings, tension
- stomach pain, often with nausea, vomiting, and diarrhoea (gastroenteritis)
- a compelling need to move (akathisia)
- dry eye

Rare (affects less than 1 in 1,000 people)

- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men (gynaecomastia)
- 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 (affects less than 1 in 10,000 people)

- muscle cramps
- small red marks on the skin
- abnormal liver function including liver failure and coma
- changes in test results – including liver and blood tests
- 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 (how often they happen is not known)

- migraine
- very high fever
- chest discomfort
- slow, fast or extra heart beats
- believing things that are not true (delusions), confusion
- excessive uncontrolled talking
- erectile dysfunction
- prolonged erections, sometimes painful, or an increased number of erections
- 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, Ritalin 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's height and weight, as well as how well your child is eating.
- If your child is not growing as expected, then treatment with Ritalin may need to be stopped.

Reporting of side effects

If you or your child 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 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 Ritalin

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 Ritalin after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package in order to protect from moisture.

If your tablets become discoloured or shows any signs of deterioration, return them to your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ritalin contains

The active substance is methylphenidate hydrochloride.

Each tablet contains 10mg of methylphenidate hydrochloride.

Other ingredients include: calcium phosphate, lactose, wheat starch, gelatine, magnesium stearate and talc.

What Ritalin looks like and contents of the pack

Ritalin Tablets are available in one strength: 10mg. White, round, flat, with beveled edges tablets measuring about 7.0 mm in diameter and about 2.6 mm in thickness. One side bears the imprint "CG", the other "A/B" and a score. May contain dark specks. The medicine is available in blister packs containing 30 tablets.

Manufacturer: INFECTOPHARM Arzneimittel und Consilium GmbH, Von-Humboldt-Straße 1, 64646 Heppenheim, Germany.

Procured from within the EEA and repackaged by PL holder: PilsCo Ltd., 10-16 Colvilles Place, East Kilbride, G75 0SN.

PL 39467/0656 Ritalin® 10mg tablets



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How do I take my medicine (tablets)?

- Your doctor will tell you how many times a day you should take your medicine
- Swallow your medicine with water.

Possible side effects

Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult you trust straight away. They can then talk to your doctor. The main things that could affect you are:

- You cannot sleep or you sleep badly
- You feel or are sick, have tummy pains or diarrhoea. It is best to take the medicine with food
- You feel worried or nervous
- You feel dizzy or get headaches
- You are very depressed and unhappy, want to hurt yourself or are unusually anxious
- You have different moods from usual or are unusually active or unusually aggressive
- You have itchy skin, skin rashes, you bruise easily
- You get out of breath
- You lose more hair than usual
- 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 beats faster than usual or irregularly
- You have poor appetite, do not grow as fast as your friends or classmates of the same age

- You have to cough, your throat hurts, or you have trouble swallowing
- You feel run down and have difficulty moving
- You have a fever

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 the number of tablets the next time. Just take the usual amount of medicine 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.

