

**Package leaflet: Information for the user**

**Ritalin® 10 mg, tablets**  
Methylphenidate Hydrochloride

The name of your medicine is Ritalin. It contains the active substance ‘methylphenidate hydrochloride’. The name ‘methylphenidate’ will also 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’.
- This 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 a 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.

**The leaflet has been written in 7 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.

1. What Ritalin is and what it is used for
2. Before you take methylphenidate

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3. How to take Ritalin
4. Possible side effects
5. How to store Ritalin
6. Further information
7. Information for children and young people

Now read the rest of this leaflet before you start taking this medicine.

## **1. What Ritalin is and what it is used for**

### **What it is used for**

Ritalin 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.

Ritalin 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**

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.

It is prescribed only by doctors who have experience in children or young people's behaviour problems. 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
- 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 (hypersensitive) to methylphenidate or any of the other ingredients of Ritalin (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 or 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 the brain – such as 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 medicine 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 your 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 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 behaviour 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

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needed before you start taking this medicine.

### **Taking other medicines**

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 anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure 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 contraception**

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 methylphenidate if you or your daughter is:

- sexually active, 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

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taking methylphenidate.

### **Driving or other 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 Ritalin**

#### **Lactose:**

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

#### **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 contain no more than 4.8 micrograms of gluten.

If you have wheat allergy (different from coeliac disease) you should not take this medicine.

## **3. How to take Ritalin**

### **How much to take**

Always take Ritalin 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 dose is 40 mg.
- Take Ritalin once or twice daily (e.g. at breakfast and/or lunchtime).
- The tablets should be swallowed with a drink of water.
- You can break the tablets to make it easier to swallow.

### **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 Ritalin properly**

If Ritalin is not used properly, this may cause abnormal behaviour. 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 Ritalin 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 and rhabdomyolysis.

### **If you forget to take Ritalin**

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 Ritalin**

If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted side effects such as depression may appear. Your doctor may want to gradually reduce the amount of

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medicine taken each day, before stopping it completely. Talk to your doctor before stopping Ritalin.

### **Things your doctor will do when you are on treatment**

Your doctor will do some tests:

- Before you start – to make sure that Ritalin 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 Ritalin.

### **Long-term treatment**

Ritalin does not need to be taken forever. If you take Ritalin 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 that 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

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- 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
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering

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**

- high temperature (fever)
- unusual hair loss or thinning
- itching, rash or raised red itchy rashes (hives)
- cough, sore throat or nose and throat irritation
- feeling unusually sleepy or drowsy
- feeling dizzy, movements which you cannot control, being unusually active
- unexpected changes in mood, feeling aggressive, agitated, anxious, depressed, irritable and abnormal behaviour
- dry mouth
- loss of appetite or decreased appetite
- high blood pressure, fast or uneven heart beat (tachycardia or palpitations)
- 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.
- excessive sweating,

**Uncommon (may affect up to 1 in 100 people)**

- constipation
- shaking or trembling
- muscle pain, muscle twitching
- blood in the urine
- double vision or blurred vision
- increases in liver test results (seen in a blood test)
- shortness of breath or chest pain
- chest discomfort
- sudden 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
- signs of psychosis such as seeing, feeling or hearing things that are not real, anger, suicidal feelings, mood swings, feeling restless or tearful, uncontrolled speech and body movements or

excessive awareness of surroundings, problems sleeping

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

- changes in sex drive
- dilated pupils, trouble sleeping
- swelling of the breasts in men
- redness of the skin, red raised skin rash
- feeling disoriented, excited, over-active and un-inhibited (mania)

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

- heart attack
- sudden death
- fits or seizures
- muscle cramps
- inflammation or blocked arteries in the brain
- changes in test results – including liver and blood tests
- abnormal liver function including liver failure and coma
- small red marks on the skin, flaking or peeling of the skin, purplish red patches
- suicidal attempt, abnormal feeling, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon')
- 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
- 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**
- migraine
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- severe stomach pain, often with feeling and being sick
- believing things that are not true, thought disturbances, confusion
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- excessive uncontrolled talking
- nosebleed

**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.

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.

**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 HPRC Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety

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of this medicine.

## **5. How to store Ritalin**

Keep this medicine out of the sight and reach of children. 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 25°C. Store the tablets in the original container in order to protect from moisture.

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. Further information**

### **What Ritalin contains**

The active substance is methylphenidate hydrochloride. Ritalin tablets contain 10mg of methylphenidate hydrochloride.

The other ingredients are: calcium phosphate, lactose monohydrate, wheat starch, gelatin, magnesium stearate and talc.

### **What Ritalin looks like and contents of the pack**

The tablets are white, circular, flat bevelled edged with a breakline, marked 'CG' on one side and 'AB' on the other side. May contain dark specks.

Ritalin tablets are available in one strength: 10 mg. The medicinal product is available in blister packs containing 30 tablets.

### **Marketing Authorisation Holder and Manufacturer**

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## **7. 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 (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 (you) 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, tell an adult you trust straight away. They can then talk to your doctor. The main things that

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could affect you are:

- Feeling or being sick, or having tummy pains. 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 dizzy or getting head aches
- Being very depressed and unhappy or wanting to hurt yourself
- Having different moods than usual, not being able to get to sleep
- Skin rashes, bruising easily, getting out of breath
- This 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.