

Package leaflet: Information for the user

Metyrol XL 10 mg
modified-release hard capsules
Metyrol XL 20 mg
modified-release hard capsules
Metyrol XL 30 mg
modified-release hard capsules
Metyrol XL 40 mg
modified-release hard capsules
Metyrol XL 60 mg
modified-release hard capsules

methylphenidate hydrochloride

The name of this medicine is Metyrol XL 10 mg, 20 mg, 30 mg, 40 mg or 60 mg modified-release hard capsules (called Metyrol XL throughout 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 or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- 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.

The leaflet has been written in sections:

- Sections 1 to 6 are for adults, 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.

What is in this leaflet

1. What Metyrol XL is and what it is used for
2. What you need to know before you or your child take Metyrol XL
3. How to take Metyrol XL
4. Possible side effects
5. How to store Metyrol XL
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 Metyrol XL is and what it is used for

What it is used for

- Metyrol XL is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).
- It is used in children and adolescents between the ages of 6 and 18, and in adults.
 - It is used only after treatments which do not involve medicine, such as counselling and behavioural therapy, and which have been insufficient.

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

How it works

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

The medicine is given as part of a treatment programme, which usually includes:

- psychological
- educational and
- social therapy.

Metyrol XL 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.

About ADHD

Children and adolescents with ADHD find it hard:

- to sit still
- to concentrate

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

Many children and adolescents struggle to do these things. However ADHD can cause problems with everyday life. Children and adolescents 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.

Not all patients with ADHD need to be treated with medicine.

For children, the decision to use a medicine must be based on a very thorough assessment of the severity and chronic nature of the child's symptoms. ADHD does not affect intelligence.

Examinations during treatment with Metyrol XL

Your doctor will regularly check your health while you are treated with Metyrol XL (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 or your child take Metyrol XL

Do not take Metyrol XL if you or your child:

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6). If you think you are allergic, ask your doctor for advice
- have a thyroid problem
- have increased pressure in the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- take a medicine called monoamine oxidase inhibitor (MAOI) used for depression, or if you or your child took a MAOI in the past 14 days (see section "Other medicines and Metyrol XL")
- have an eating problem where you or your child 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 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 hallucinations, or an illness called 'schizophrenia'
 - signs of a severe mood problem like:
 - feeling like killing oneself
 - severe depression (feeling very sad, worthless and hopeless),
 - mania (feeling unusually excitable, over-active, and uninhibited)
 - mood changes from depression to mania

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Metyrol XL if you or your child:

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

- feeling agitated, anxious or tense
- feeling depressed or guilty

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.

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 your erection lasts for longer than 2 hours, particularly if this is painful.

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

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

- any other medicines you or your child are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you, 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.

Drug testing

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

Effects in case of misuse as doping agent

Use of Metyrol XL can lead to positive results in doping tests. Misuse of Metyrol XL for doping purposes may pose a risk to health.

Other medicines and Metyrol XL

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take Metyrol XL if you or your child:

- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression, or have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in blood pressure (see "Do not take Metyrol XL").

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. It may therefore be necessary to change the dose of the medicine or to discontinue treatment all together. 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 (e.g. schizophrenia)
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain substances that can affect blood pressure. It is important to check with your pharmacist when you buy any of these medicines
- medicines that thin the blood to prevent blood clots

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

Having an operation

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

Metyrol XL with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor 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.

No effects on fertility have been seen in animals.

Tell your doctor or pharmacist before taking this medicine if you or your daughter are:

- sexually active. Your doctor will discuss contraception
- pregnant, may be pregnant or are planning to become pregnant. Your doctor will decide whether you should take methylphenidate

- are breast-feeding or are planning to breast-feed. It is possible that methylphenidate is passed into breast milk. Therefore, your doctor will decide whether you should breast-feed while taking methylphenidate

Driving and using machines

You or your child may feel dizzy or sleepy, have problems focussing or have blurred vision, have hallucinations or other side effects of the central nervous system 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.

Metyrol XL contains sucrose

Metyrol XL contains sucrose (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 medicine.

3. How to take Metyrol XL

You or your child should always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose

Your doctor will usually start treatment with a low dose and increase it gradually as required.

Children (6 years and over) and adolescents

The recommended starting dose is 20 mg once daily. At the discretion of the doctor, treatment with Metyrol XL can also be started at a dose of 10 mg. The maximum daily dose is 60 mg once daily. Metyrol XL is taken once daily in the morning in patients younger than 18 years of age.

Adults

- If you take Metyrol XL for the first time, your doctor will start your treatment at a dose of 20 mg once daily and, if required, will increase the dose gradually at weekly small increments.
- If you were already treated with a modified-release formulation of methylphenidate during childhood and you have recently turned 18 years of age, your doctor may continue treatment with the same dose. If you were treated with an immediate-release formulation during childhood, your doctor will prescribe the equivalent dose of Metyrol XL.

The maximum daily dose is 80 mg.

For lower doses or smaller increments different strengths of this medicine and other methylphenidate-containing medicines may be available.

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

Your doctor will do some tests:

- before you or your child starts – to make sure that Metyrol XL is safe and will be of benefit (listed in section "Checks that your doctor will make before you or your child starts taking methylphenidate").
- after you or your child starts – 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 appetite
- measuring height and weight in children
- measuring weight in adults
- measuring blood pressure and heart rate
- checking for problems with mood, state of mind or any other unusual feelings, or if these have become worse while taking Metyrol XL

Method of administration

Metyrol XL is for oral use.

- Take Metyrol XL once daily in the morning. Metyrol XL should not be taken too late in the morning as it may cause disturbances in sleep.
- The capsule can be taken with or without food.
 - The capsule should be swallowed whole, with a glass of water.
 - Do not crush, chew or divide the capsule or its contents.

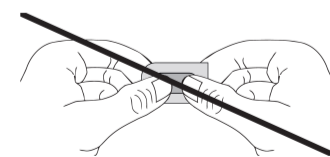
If you or your child are unable to swallow Metyrol XL you can sprinkle the contents on a small amount of food, as follows:

- Carefully open the capsule and sprinkle the pellets over a small amount of soft food (e.g. apple sauce).
- The food should not be warm because this could affect the special properties of the pellets.
- Immediately eat all of the medicine/food mixture. Do not store any medicine/food mixture for future use.

Opening instruction for the blister

This medicine is available in peelable, child resistant blisters. Please observe the following opening instruction for the blister:

1. Do not push the capsule out of the blister, as this will crush it.



2. Take the blister with the printed foil up and bend it backwards along the perforated line. Bend the blister in the opposite direction and tear along the cross-perforation.

