

Package leaflet: Information for the user

Equasym® XL 40 mg, 50 mg and 60 mg modified-release capsules, hard methylphenidate hydrochloride

The name of this medicine is Equasym XL, it contains the active substance ‘methylphenidate hydrochloride’. The name ‘methylphenidate’ will also be used in this leaflet.

Read all of this leaflet carefully before you or your child 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 or your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Equasym XL is and what it is used for

What it is used for

Equasym XL 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.

Equasym XL 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

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

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

- psychological
- educational and
- social therapy

Methylphenidate treatment must only be started by, and used under the regular check-ups of, a specialist in childhood and/or adolescent behavioural disorders.

ADHD 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. What you need to know before you take Equasym XL

Do not take methylphenidate if you or your child:

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in Section 6)
- have a thyroid problem
- have increased pressure in the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- have an eating problem when you do not feel hungry or want to eat - such as ‘anorexia nervosa’
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or were born with a heart problem
- have had a problem with the blood vessels in 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)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) – see Taking other medicines
- 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 or your child. If you are not sure, talk to your doctor or pharmacist before you or your child take methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

Tell your doctor or pharmacist before taking treatment 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 a female and have started having 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 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 or your child before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

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

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 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, 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 methylphenidate is the correct medicine for you or your child. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Other medicines and Equasym XL

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

Do not take methylphenidate 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.

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you or your child are taking any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:

- other medicines for depression
- medicines for severe mental health problems
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots

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

Please tell your doctor or pharmacist if you or your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

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.

Drug testing

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

Methylphenidate with alcohol

Do not drink alcohol whilst 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.

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

- having sex. Your doctor will discuss contraception
- pregnant or may be pregnant. Your doctor will decide whether methylphenidate should be taken
- breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk. Therefore, your doctor will decide whether you or your daughter should breast-feed while taking methylphenidate.

Prolonged erections

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important you or your child contact your doctor straight away if an erection lasts for longer than 2 hours, particularly if this is painful.

Driving and using machines

You or your child 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.

Equasym XL contains sucrose (a type of sugar).

If you or your child has an intolerance to some sugars, talk to your doctor before taking this medicine.

Equasym XL contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per capsule, so it is essentially 'sodium-free'.

3. How to take Equasym XL

How much to take

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

- Equasym XL is a "modified release" form of methylphenidate which releases the medicine gradually over a time period corresponding to the school day (8 hours). It is intended to take the place of the same total daily dose of traditional (immediate release) methylphenidate taken at breakfast and lunchtime.
- If you or your child are already taking traditional (immediate release) methylphenidate, your doctor may prescribe an equivalent dose of Equasym XL instead.
- If you or your child have not taken methylphenidate before, your doctor will normally start treatment with traditional (immediate release) methylphenidate tablets. If your doctor feels it is necessary methylphenidate treatment may be started with Equasym XL 10 mg once daily before breakfast.
- Your doctor will usually start treatment with a low dose and increase it gradually as required.
- The maximum daily dose is 60 mg.

How to take

- Equasym XL should be given in the morning before breakfast. The capsules may be swallowed whole with a drink of water, or alternatively, may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of apple sauce and taken/given immediately and not stored for future use. If the medicine is taken/given with soft food, some fluids, e.g. water, should be taken afterwards.

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 need a different treatment.

Not using Equasym XL properly

If Equasym XL is not used properly, this may cause abnormal behaviour. It may also mean that you or your child start to depend 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 their symptoms seem similar.

If you or your child take more Equasym XL 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.

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 or psychosis), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you or your child forget to take Equasym XL

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

If you or your child stop taking Equasym XL

If you or your child suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Equasym XL. If you have any further questions on the use of this medicine, ask your doctor, or pharmacist or nurse.

Things your doctor will do when you or your child are on treatment**Your doctor will do some tests**

- before you or your child start - to make sure that Equasym XL is safe and will be of benefit.
- after you or your child 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 appetite
 - measuring height and weight
 - measuring blood pressure and heart rate
 - checking problems with mood, state of mind or any other unusual feelings. Or if these have got worse while taking Equasym XL.

Long-term treatment

Equasym XL does not need to be taken for ever. If you or your child take Equasym XL for a longer time, your doctor should stop treatment for some time, at least once a year, 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, this medicine 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 or your child have any of the side effects below, see a doctor straight away:

Common (affects less than 1 in 10 people)

- uneven heartbeat (palpitations)
- mood changes or mood swings or changes in personality

Uncommon (affects less than 1 in 100 people)

- thinking about or feeling like killing yourself
- seeing, 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 (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
- 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 or increase 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)

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 (affects more than 1 in 10 people)

- headache
- feeling nervous
- not being able to sleep

Common (affects less than 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
- itching, rash or raised red itchy rashes (hives)
- cough, sore throat or nose and throat irritation
- high blood pressure, fast heartbeat (tachycardia)
- feeling dizzy, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable and abnormal behaviour
- excessive teeth grinding (bruxism)

Uncommon (affects less than 1 in 100 people)

- constipation
- chest discomfort
- blood in the urine
- shaking or 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

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
- excessive sweating, redness of the skin, red raised skin rash

Very rare (affects less than 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, completed suicide, abnormal thinking, 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')

Other side effects (how often they happen is not known)

- migraine
- excessive talkativeness
- very high fever
- slow, fast or extra heart beats
- nosebleed
- a major fit ('grand mal convulsions')
- believing things that are not true, confusion
- severe stomach pain, often with feeling and being sick
- prolonged erections, sometimes painful. or an increased number of erections, inability to develop or maintain an erection
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- bruising
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering

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 you or your child's height and weight, as well as how well you or your child are eating.
- If you or your child are not growing as expected, then your treatment with methylphenidate may be stopped for a short time.

If you have any of the side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Equasym XL

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not use this medicine if the capsules look damaged in any way.

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 to protect the environment.

6. Contents of pack and other information

What Equasym XL contains

The active substance is methylphenidate hydrochloride.

- Each 40 mg capsule contains 40 mg of methylphenidate hydrochloride corresponding to 34.59 mg of methylphenidate.
- Each 50 mg capsule contains 50 mg of methylphenidate hydrochloride corresponding to 43.24 mg of methylphenidate.
- Each 60 mg capsule contains 60 mg of methylphenidate hydrochloride corresponding to 51.89 mg of methylphenidate

The other ingredients are:

- **Capsule content:** Sugar spheres (sucrose and maize starch), povidone K29 to K32, Opadry Clear Ys-1-7006 (hypromellose, macrogol 400 and macrogol 8000), ethylcellulose aqueous dispersion and dibutyl sebacate
- **Capsule shell:** Gelatin, Titanium dioxide (E171). The 40 mg capsule also contains yellow iron oxide (E172) and the 50 mg capsule also contains indigo carmine (E132) and red iron oxide (E172)
- **White printing ink:** shellac, propylene glycol, sodium hydroxide, povidone K16 and titanium dioxide (E171)
- **Black ink** contains shellac glaze 45% (20% esterified) in ethanol, propylene glycol, ammonium hydroxide 28% and iron oxide black (E172)

What Equasym XL looks like and contents of the pack

Modified-release capsules, hard

The 40 mg modified-release capsules, hard have a yellow ivory opaque cap imprinted with “S544” in black and a white opaque body imprinted with “40 mg” in black.

The 50 mg modified-release capsules, hard have a purple opaque cap imprinted with “S544” in white and a white opaque body imprinted with “50 mg” in black.

The 60 mg modified-release capsules, hard have a white opaque cap imprinted with “S544” in black and a white opaque body imprinted with “60 mg” in black.

Pack sizes: 28 or 30 modified-release capsules, hard.

Not all pack sizes or strengths may be marketed.

Marketing Authorisation Holder and Manufacturer

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium	Equasym XR
Denmark	Equasym Depot
Finland	Equasym Retard
France	Quasym
Germany	Equasym Retard
Iceland	Equasym Depot
Ireland	Equasym XL
Italy	Equasym
Luxembourg	Equasym XR
Netherlands	Equasym XL
Norway	Equasym Depot
Portugal	Quasym
Spain	Equasym
United Kingdom (Northern Ireland)	Equasym XL

This leaflet was last revised in 01/2025

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.