

Package leaflet: Information for the user

Meflynate XL 10 mg modified-release hard capsules

Meflynate XL 20 mg modified-release hard capsules

Meflynate XL 30 mg modified-release hard capsules

Meflynate XL 40 mg modified-release hard capsules

Meflynate XL 60 mg modified-release hard capsules

methylphenidate hydrochloride

The name of your medicine is Meflynate XL; 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'.
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other treatments for ADHD as well as this medicine.

Read Section 1 for more information.

Before you take this medicine, talk to your doctor if:

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

Read Section 2 for more information.

While taking this medicine:

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

Read Sections 3 and 4 for more information.

Talk to your doctor straight away if any of the following happen:

- Your mood and how you feel changes.
- You feel any problems with your heart.

Read Section 4 for more information.

The rest of this leaflet includes more detail and other important information on the safe and effective use of this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects worry you, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

The leaflet has been written in sections:

- Sections 1 to 6 are for parents and carers (sometimes called 'your guardians').
- The last section is a special section for a child or young person to read. However, all sections are written as though the child or young person taking the medicine is reading them.

The sections are:

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

What it is used for

Meflynate 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.

Meflynate 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

Meflynate 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.

Meflynate 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.

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.

2. What you need to know before you or your child take Meflynate XL

Do not take Meflynate 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 Meflynate 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 an inherent 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 Meflynate 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 Meflynate XL"
- have a mental health problem which is not mentioned in the section "Do not take Meflynate 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 Meflycate XL can lead to positive results in doping tests. Misuse of Meflycate XL for doping purposes may pose a risk to health.

Other medicines and Meflycate XL

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

Do not take Meflycate 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 Meflycate 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 altogether. 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.

Meflycate 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.

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.

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

- is sexually active. Your doctor will discuss contraception
- is pregnant or think might be pregnant. Your doctor will decide whether methylphenidate should be taken
- is breast-feeding or 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, feel drowsy, have problems focussing or have blurred vision, have hallucinations or other side effects in 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.

Meflycate XL contains sucrose

Meflycate 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 medicinal product.

3. How to take Meflycate 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 Meflycate XL can also be started at a dose of 10 mg. The maximum daily dose is 60 mg once daily. Meflycate XL is taken once daily in the morning in patients younger than 18 years of age.

Adults

- If you take Meflycate 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 Meflycate 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 Meflycate 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 Meflycate XL

Method of administration

Meflycate XL is for oral use.

Take Meflycate XL once daily in the morning. Meflycate 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.

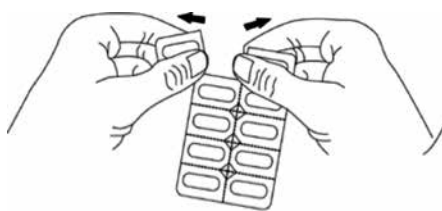
If you or your child are unable to swallow Meflycate XL you can sprinkle the contents on a small amount of food, as follows:

- 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.



3. Pull off a single dose by tearing along the perforated line on the blister and peel back the foil on the blister to expose the capsule.



Long-term treatment

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

If you or your child do not feel better after 1 month of treatment

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

Not using Meflynate XL properly

If Meflynate 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 Meflynate XL than you should

If you or your child have taken too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Medical treatment might be needed.

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 and dry nose and mouth, muscle swelling, weak, tender and sore muscles, dark urine.

If you or your child forget to take Meflynate 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 Meflynate 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 Meflynate XL.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will talk to you about these side effects.

Some side effects could be serious. If you or your child experience any of the side effects below, see a doctor straight away:

Common (may affect up to 1 in 10 people)

- uneven heartbeat (palpitations)
- changes in personality
- excessive teeth grinding (bruxism)

Uncommon (may affect up to 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 Syndrome)
- 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

- mood changes or mood swings

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

- feeling unusually excited, over-active and uninhibited (mania)

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

- heart attack
- fits (seizures, epilepsy with convulsions)
- skin peeling or purplish red patches
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system - due to a temporary lack of blood supply to the brain
- paralysis or problems with movement and vision, difficulties in speech - these can be signs of problems with the blood vessels in your brain
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other medicines 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)
- inability to control the excretion of urine (incontinence)
- spasm of jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering.

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)

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

Common (may affect up to 1 in 10 people)

- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite
- weight decrease 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 or chest pain
- changes in blood pressure (mainly high blood pressure),
- fast heart beat (tachycardia),
- cold hands and feet
- shaking or trembling, feeling dizzy, movements which you cannot control, feeling of inner restlessness,
- 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. These side effects usually occur at the start of treatment and can be reduced by taking the medicine with food.

Uncommon (may affect up to 1 in 100 people)

- constipation
- chest discomfort
- inflammation of the mucous membranes of stomach and small intestine
- blood in the urine
- double vision or blurred vision

Information for children and young people

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

If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.

It may help if you read small bits at a time.

Why have I been given this medicine?

This medicine can help children and young people with 'ADHD'.

- ADHD can make you:
 - run about too much
 - not be able to pay attention
 - act quickly without thinking about what will happen next (impulsive)
- It affects learning, making friends and how you think about yourself. It is not your fault

While you are taking this medicine

- As well as taking this medicine you will also get help with ways to cope with your ADHD such as talking to ADHD specialists

- This medicine should help you, but it does not cure ADHD
- You will need to go to your doctor several times a year for 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
- Do not drink alcohol. Alcohol may make the side effects of this medicine worse
- If you are having sex, please talk to your doctor about contraception. Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies

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

- muscle pain, muscle twitching, muscle tightness
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings, tension

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

- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men
- redness of the skin, red raised skin rash

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

- heart attack
- sudden death
- muscle cramps
- small red marks on the skin
- inflammation or blocked arteries in the brain
- abnormal liver function including liver failure and coma
- changes in test results including liver and blood tests
- suicide attempt (including 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')

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')
- believing things that are not true, confusion
- severe stomach pain, often with feeling and being sick
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- erectile dysfunction
- prolonged erections, sometimes painful, or an increased number of erections
- excessive uncontrolled talking
- nosebleed

Effects on growth

When used for more than one 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 increase.
- Your doctor will carefully monitor height and weight, as well as how well you or your child are eating.
- If your child is not growing as expected, then treatment with methylphenidate may be stopped for a short time.

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 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 Meflynate 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 carton box and blister after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.



How do I take my medicine?

- 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 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 headaches
- 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
- The medicine can also make you feel sleepy. If you feel sleepy, it is important not to do outdoor sports like riding a

6. Contents of the pack and other information

What Meflynate XL contains

- The active substance is methylphenidate hydrochloride. Meflynate XL 10 mg modified-release hard capsules contain 10 mg methylphenidate hydrochloride (equivalent to 8.65 mg methylphenidate). Meflynate XL 20 mg modified-release hard capsules contain 20 mg methylphenidate hydrochloride (equivalent to 17.3 mg methylphenidate). Meflynate XL 30 mg modified-release hard capsules contain 30 mg methylphenidate hydrochloride (equivalent to 25.95 mg methylphenidate). Meflynate XL 40 mg modified-release hard capsules contain 40 mg methylphenidate hydrochloride (equivalent to 34.6 mg methylphenidate). Meflynate XL 60 mg modified-release hard capsules contain 60 mg methylphenidate hydrochloride (equivalent to 51.9 mg methylphenidate)

- The other ingredients are:
Capsule contents: ammonio methacrylate copolymer (type B), methacrylic acid-methyl methacrylate copolymer (1:1), povidone 30, sugar spheres, talc, triethyl citrate.
Capsule shell: gelatin, titanium dioxide (E171).
Additionally in Meflynate XL 10 mg modified-release hard capsules, Meflynate XL 30 mg modified-release hard capsules, Meflynate XL 40 mg modified-release hard capsules and Meflynate XL 60 mg modified-release hard capsules: Iron oxide yellow (E172).

Printing ink: potassium hydroxide, propylene glycol, red iron oxide (E172), shellac glaze, strong ammonia solution.

What Meflynate XL looks like and contents of the pack

Meflynate XL 10 mg modified-release hard capsules
Hard gelatin capsule size 2, with a dark yellow opaque cap and a white opaque body, imprinted with "RUB" in red ink on the cap and "M10" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.

Meflynate XL 20 mg modified-release hard capsules
Hard gelatin capsule size 2, white opaque capsule, imprinted with "RUB" in red ink on the cap and "M20" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.

Meflynate XL 30 mg modified-release hard capsules
Hard gelatin capsule size 2, ivory opaque capsule, imprinted with "RUB" in red ink on the cap and "M30" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.

Meflynate XL 40 mg modified-release hard capsules
Hard gelatin capsule size 1, dark yellow opaque, imprinted with "RUB" in red ink on the cap and "M40" in red ink on the body, containing white and whitish pellets. Capsule length: 20 mm.

Meflynate XL 60 mg modified-release hard capsules
Hard gelatin capsule size 0, with a dark yellow opaque cap and an ivory opaque body, imprinted with "RUB" in red ink on the cap and "M60" in red ink on the body, containing white and whitish pellets. Capsule length: 22 mm.

Child resistant blisters Aclar/PVC/Al/PET boxed in cardboard cartons.

Pack sizes:

- 10 mg: 28, 30, 50, 56, 60, 100 capsules.
- 20 mg: 28, 30, 50, 56, 60, 84, 100 capsules.
- 30 mg: 28, 30, 50, 54, 56, 60, 100 capsules.
- 40 mg: 28, 30, 50, 54, 56, 60, 100 capsules.
- 60 mg: 28, 30, 40, 50, 56, 60, 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Flynn Pharma Limited
5th Floor,
40 Mespil Road,
Dublin 4,
IRELAND, D04 C2N4

Manufacturer:

Laboratorios Rubió, S.A.
Calle Industria, 29. Pol. Ind. Comte de Sert
08755 Castellbisbal (Barcelona)
Spain

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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 capsules the next time. Just take one capsule 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

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PRODUCT:

Meflynate XL modified-release
hard capsules ALL Leaflet UK

Job No: FF48

Date: 24.2.23

Component: Leaflet (PIL)

Dimensions: 195x385 mm (2 sheets)

Colours:

Black ■

Fonts: (Artwork)

DIN font family
min 9 pts

Software used:

Indesign CC

Amends:

Draft: 2

Rev date: 1.6.23

Reviser:

Artwork Sign-off(dig-
itally):

Approval:

Internal proof approval

Signed (digitally)

External proof approval

Signed (digitally)