

PACKAGE LEAFLET

Package leaflet: Information for the patient
Mianserin 10 mg film-coated tablets
Mianserin 30 mg film-coated tablets

(mianserin hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. 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 Mianserin is and what it is used for
2. What you need to know before you take Mianserin
3. How to take Mianserin
4. Possible side effects
5. How to store Mianserin
6. Contents of the pack and other information

1. What Mianserin is and what it is used for

Mianserin belongs to a group of medicines called tetra-cyclic antidepressants. Mianserin is believed to work by increasing the levels of two naturally occurring chemicals within the brain, noradrenaline and 5 hydroxytryptamine (also called serotonin). Your doctor will prescribe Mianserin to help relieve the symptoms of depression.

2. What you need to know before you take Mianserin

Do not take Mianserin if you:

- are allergic to mianserin or any of the other ingredients of this medicine (listed in section 6)
- suffer from severe liver disease
- have been or are being treated for mania (feeling over-excited with unusual behaviour)
- are breast-feeding (refer to the 'Pregnancy and breast-feeding' section of this leaflet)
- are also taking the following medicines used to treat depression:
 - a monoamine oxidase inhibitor (MAOI). You should not take mianserin at the same time or within 2 weeks of taking an MAOI. If you have taken mianserin, you should wait 1-2 weeks before you take a MAOI
 - a selective reversible monoamine oxidase inhibitor (MAO-A inhibitor) such as moclobemide. You should not start taking mianserin within 1 week of taking an MAO-A inhibitor.

Warnings and precautions

Talk to your doctor or pharmacist before taking mianserin if you:

- have ever had an epileptic seizure (a fit), or are at risk of having one due to any of the following reasons:
 - head injury
 - taking or stopping medicines for mental health conditions (which can make you feel very sleepy or may possibly cause fitting as a side effect)
 - stopping medicines that control seizures (fits), or you are
 - reducing the amount of alcohol you are drinking

- have a heart disorder such as cardiovascular insufficiency (when the heart cannot pump enough blood around the body). In this case your doctor may monitor your heart function
- are recovering from a recent heart attack (myocardial infarction) or suffer from a condition known as heart block, or have an abnormal heart rhythm
- suffer from manic depressive illness
- are pregnant (refer to the 'Pregnancy and breast-feeding' section of this leaflet)
- suffer from a tumour in your adrenal gland (phaeochromocytoma)
- are diabetic, as your diabetic medicine may need to be adjusted
- have kidney or other liver problems
- have, or have had in the past:
 - raised pressure in the eye (in particular an eye condition called narrow-angle glaucoma)
 - urinary retention (difficulty passing urine) or symptoms of obstruction of the neck of the bladder (e.g. due to an enlarged prostate gland).

Blood tests

This medicine may affect your blood or the way your liver works. You will need regular blood tests – usually every 4 weeks during the first 3 months of treatment. Tell your doctor straight away if you develop a fever, sore throat, sore mouth or any other signs of an infection.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

Mianserin should not normally be used by children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines.

Despite this, your doctor may prescribe mianserin for patients under 18 because he or she decides that this is in their best interests. If your doctor has prescribed mianserin for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking mianserin. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of mianserin in this age group have not yet been demonstrated.

Other medicines and Mianserin

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

- medicines that affect the way your blood clots, e.g. warfarin and other 'coumarins' (blood thinning medicines)

- medicines for depression particularly MAOIs e.g. tranylcypromine, phenelzine and selective reversible monoamine oxidase inhibitors (MAO-A inhibitors) e.g. moclobemide (see “Do not take” above) medicines to help you sleep, feel less anxious, or for mental health conditions
- any medicine for epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone
- diazoxide, hydralazine, nitroprusside or any other medicine used to treat high blood pressure
- medicines for chest pain (angina) which are dissolved under the tongue
- medicines for allergy (antihistamines – in some cases these may also be given to help you sleep, such as diphenhydramine)
- artemether with lumefantrine, used to treat malaria
- atomoxetine, used in the treatment attention deficit hyperactivity disorder (ADHD)
- apraclonidine or brimonidine, eye drops used to treat glaucoma (raised pressure in the eyes), or eye drops to dilute the pupil (such as atropine)
- sibutramine, used to help weight loss
- medicines known as ‘anti-muscarinics’. These may be used to treat lung problems (such as tiotropium, ipratropium), bowel spasms (such as dicycloverine, hyoscine), Parkinson’s disease (such as procyclidine), or problems with urinating (such as bethanechol)

Surgery

If you are going to be given a general anaesthetic for an operation or a local anaesthetic for a small operation or dental procedure let your anaesthetist or dentist know that you are taking this medicine.

Mianserin with alcohol

Do not drink alcohol whilst taking this medicine. Alcohol can make the feeling of drowsiness worse.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is limited information on the use of Mianserin during pregnancy and therefore you **should not** take Mianserin if you are pregnant, think you may be pregnant or are trying to become pregnant. If taken during pregnancy, there is a risk of withdrawal symptoms in the baby after birth, such as irritability.

Mianserin may reach your baby through the breast milk. Therefore, **do not** take Mianserin if you are breast-feeding.

Driving and using machines

Do not drive or operate machinery because this medicine may make you feel drowsy and can cause blurred vision. Alcohol can make the feeling of drowsiness worse.

3. How to take Mianserin

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

The tablets should be swallowed whole with a drink of water. Do not chew them.

Duration of treatment

You should take your tablets for as long as your doctor says. Remember that you may need to take Mianserin for 2 to 4 weeks before you begin to feel better (see also section 2). So **do not** stop taking this medicine just because you do think that it is not working. You may need to take these tablets for a long time.

Your dose will be adjusted so that it is right for you and helps control the symptoms of your illness.

The recommended dose is:

Adults

The recommended starting dose is 30 mg or 40 mg per day, increasing gradually, normally up to a maximum of 90 mg per day. Your dose may be taken as a single dose at bedtime (which may help you sleep) or split into 2 or 3 doses taken throughout the day.

Older people

The recommended starting dose is 30 mg per day. Your doctor may carefully increase this as needed, to a maximum dose which may be lower than that recommended for younger patients. It is recommended that your dose is taken as a single dose at bedtime.

Use in children and adolescents

Mianserin is **not** recommended in children and adolescents (see also section 2).

If you take more Mianserin than you should

Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you.

You may have the following symptoms: you may feel or be sick, have a dry mouth, closed or wide open pupils, rapid uncontrollable movements of the eye, feel dizzy, drowsy, shaky or unsteady or experience convulsions (fits) or fall into a coma. In addition, you may notice a slow or fast heartbeat, have low or raised blood pressure (these may make you feel faint), or experience changes in the heart rhythm which could cause the heart to stop.

If you forget to take Mianserin

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Mianserin

Speak to your doctor first before stopping this medicine. Your doctor will tell you how to gradually reduce your medication. This will help avoid unwanted side effects such as sweating, shaking, being sick, feeling sick, aggression, anxiety, or experiencing blurred vision or hallucinations (seeing or hearing things that are not real).

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.

If you begin to experience any of the following side effects stop taking Mianserin and **contact your doctor immediately**:

- Sore throat, mouth ulcers, cold sores, or other infections, inflammation of the mouth lining, fever, feeling tired, weak or pale. These may be signs of changes in the numbers of certain blood cells which may indicate a problem with the bone marrow (where these cells are produced), more common in elderly patients
- Thoughts of harming or killing yourself, or behaviours consistent with trying to harm or kill yourself
- Fits (convulsions)
- Yellowing of the skin or whites of the eyes
- A feeling of elated mood which may mean that you make unusual decisions or may not consider other people. Your speech may be fast and animated, sex drive may be increased, and you may be very persistent or irritable

Other possible side effects include:

- Feeling very elated or over-excited, which can rapidly change to irritability. Speech may be very rapid and incoherent and unusual behaviour which may be extravagant, overbearing or violent may occur

- Feelings or beliefs which are not consistent with reality, which may include thoughts that other people are trying to harm you
- Interference with sexual function in adults
- Breast enlargement in men
- Nipple tenderness
- Production of breast milk (in men, or in women who are not expecting to produce milk)
- Disturbances of liver function, or low levels of sodium in the blood (these may show up in blood tests, more common in elderly patients)
- Joint pain and swollen joints
- Dizziness, light-headedness or fainting on standing up (these may be a sign of low blood pressure).
- Fluid retention
- Skin rash
- Sweating
- Shaking

If you stop taking the medicine, you may get withdrawal symptoms such as sweating, shaking, being sick, feeling sick, aggression, anxiety, or experience blurred vision or hallucinations (seeing or hearing things that are not real)

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mianserin

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 pack after “EXP”. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from moisture and light.

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 the pack and other information

What Mianserin contains

The active substance is mianserin hydrochloride. Each 10 mg film-coated tablet contains 10 mg mianserin hydrochloride. Each 30 mg film-coated tablet contains 30 mg mianserin hydrochloride.

The other ingredients are: maize starch, pregelatinised, silica, colloidal anhydrous, cellulose, microcrystalline, calcium hydrogen phosphate and magnesium stearate. The film coating of the tablets contains titanium oxide (E171), hypromellose, macrogol 400 and talc.

What Mianserin looks like and contents of the pack

Mianserin film-coated tablets are white film-coated tablets. 10 mg film-coated tablets are embossed with “MI 10” on one side and “G” on the other side. 30 mg film-coated tablets are embossed with “MI 30” on one side and “G” on the other side.

The tablets are available in plastic containers (which may also contain an optional plastic spacer at the top of the pack) or blister packs of 28, 30, 56, 60, 84, 90, 100, 112, 250, 500 or 1000 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mylan,
Potters Bar, Hertfordshire, EN6 1TL, UK

Manufacturers

Generics [UK] Limited,
Station Close, Potters Bar, Hertfordshire, EN6 1TL, UK

Gerard Laboratories, 35/36 Baldoyle Industrial
Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft.,
Mylan utca 1., Komárom, 2900, Hungary

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