

Mirtazapine GH

mirtazapine tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Mirtazapine GH.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT MIRTAZAPINE GH IS USED FOR

This medicine is used to treat depression.

It contains the active ingredient mirtazapine.

Mirtazapine belongs to a group of medicines called antidepressants.

It works by correcting chemical imbalances in parts of the brain and may help relieve the symptoms of depression. Chemical imbalances in parts of the brain are thought to cause depression.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

BEFORE YOU TAKE MIRTAZAPINE GH

When you must not take it

Do not take this medicine if you have an allergy to:

- mirtazapine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
 - wheezing or difficulty breathing
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- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days.

Examples of MAOIs include phenelzine, tranylcypromine and selegiline.

Taking this medicine with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Do not give this medicine to children or adolescents under the age of 18 years.

Safety and effectiveness in children and adolescents younger than 18 years has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- thoughts of suicide or self harm
- epilepsy (fits or convulsions)
- liver problems
- kidney problems
- heart problems
- low blood pressure (hypotension)
- mental conditions such as schizophrenia or manic depression (alternating periods of elevation/overactivity and depressed mood)
- diabetes
- an enlarged prostate resulting in difficulties in urination
- glaucoma (increased pressure in your eyes)
- unexplainable high fever, sore throat or mouth ulcers
- galactose intolerance
- glucose-galactose malabsorption.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking Mirtazapine GH.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Mirtazapine GH may interfere with each other. These include:

- other medicines used to treat depression, panic attacks, anxiety disorders, obsessive compulsive

- disorders or pre-menstrual dysphoric disorder, such as SSRIs or venlafaxine
- monoamine oxidase inhibitors (MAOIs) such as tranylcypromine, phenelzine and selegiline
 - medicines containing St John's Wort (*Hypericum perforatum*), a herbal remedy
 - medicines used for fungal infections, such as ketoconazole
 - medicines used to treat HIV/AIDS
 - medicines used to treat stomach ulcers, reflux or heartburns, such as cimetidine
 - medicines used to treat epilepsy, such as phenytoin and carbamazepine
 - benzodiazepines or other medicines used to treat anxiety and sleeping problems
 - warfarin, a medicine used to prevent blood clots
 - erythromycin, an antibiotic used to treat bacterial infections
 - rifampicin, a medicine used to treat tuberculosis
 - triptans such as sumatriptan, naratriptan and zolmitriptan, medicines used to treat migraines.

These medicines may be affected by Mirtazapine GH or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE MIRTAZAPINE GH

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Mirtazapine GH may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

If you need to break Mirtazapine GH 30mg tablets in half, hold the tablet with both hands and snap along the break line.



When to take Mirtazapine GH

Take your medicine at about the same time each day, preferably as a single night-time dose before going to bed.

Taking it at the same time each day will help you remember when to take it.

If recommended by your doctor, this medicine may be taken in sub-doses equally divided over the day (for example, once in the morning and once at night-time before going to bed).

How long to take Mirtazapine GH

Continue taking your medicine for as long as your doctor tells you.

For depression, the length of treatment depends on how quickly your symptoms improve.

Most antidepressants take time to work. Some symptoms may improve in 1 to 2 weeks, but it can take up to 2 to 4 weeks to feel the full benefit of the medicine.

It is important to keep taking your medicine even if you feel well, usually for about 4 to 6 months or even longer, to make sure the benefits will last.

If you forget to take it

Once daily dosing:

If you forget to take the tablet before you go to bed, do not take the missed dose the next morning.

This medicine may cause drowsiness or sleepiness during the day.

Continue treatment in the evening with your usual dose, and continue to take it as you would normally.

Twice daily dosing:

- **If you forget your morning dose:** take your morning dose together with your evening dose.
- **If you forget your evening dose:** do not take it with the next morning dose. Continue treatment with your usual evening dose, and continue to take it as you would normally.
- **If you forget both doses:** do not try to make up for missed doses. Continue treatment with your usual morning and evening dose the next day.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Mirtazapine GH. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- drowsiness
- dizziness
- confusion
- agitation
- increased heart rate
- tremors
- fainting.

WHILE YOU ARE TAKING MIRTAZAPINE GH

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Mirtazapine GH.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Do not stop taking your tablets until you have spoken to your doctor.

If you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections, tell your doctor immediately.

If you have any suicidal thoughts or other mental/mood changes, tell your doctor immediately or go to the nearest hospital for treatment.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. Until the full effects of your medicine becomes apparent, these symptoms may increase in the first few weeks of treatment.

If you or someone you know is showing signs of suicide-related behaviour while taking Mirtazapine GH, contact your doctor or a mental health professional immediately or go to the nearest hospital for treatment.

These signs include:

- thoughts or talk about death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

Any mention of self-harm, violence or suicide must be taken seriously.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood tests from time to time. This helps to prevent unwanted side effects.

Tell your doctor if you feel the tablets are not helping your condition.

Tell your doctor if you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not drive or operate machinery until you know how Mirtazapine GH affects you.

This medicine may cause drowsiness, dizziness or sleepiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Do not take Mirtazapine GH to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as nausea, headache, dizziness, anxiety and agitation.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, drowsiness or dizziness may be worse. You may also feel less alert.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mirtazapine GH.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness or sleepiness, especially during the first weeks of treatment
- dizziness or feeling faint, especially when standing up quickly from a lying or sitting position
- rash
- headache
- increase in appetite and weight gain
- dry mouth
- diarrhoea
- swollen ankles or feet due to fluid accumulation (oedema)
- trouble concentrating
- nightmares/vivid dreams
- tingling fingers or toes
- muscle or joint aches and pains
- restless legs
- anxiety or problems sleeping*.

*Anxiety or problems sleeping may be symptoms of depression.

Tell your doctor immediately if you notice any of the following:

- any symptoms of infections such as fever, sore throat or mouth ulcers, gastrointestinal (stomach or bowel) disturbances.

In very rare cases, Mirtazapine GH may reduce your ability to fight infections. Symptoms of this rare side effect usually appear after about 2 to 6 weeks of treatment. This side effect is usually reversible after stopping treatment.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing

- wheezing or shortness of breath
- skin rashes, itching or hives
- fainting
- fits or seizures
- shaking or tremors
- muscle spasms, twitching or sudden muscle contractions (myoclonus)
- attack of excessive excitability (mania)
- confusion
- hallucinations
- very agitated or restless behaviour
- yellowing of the eyes and/or skin (jaundice)
- generalised fluid retention with weight gain
- changes in heart rate or rhythm, chest pain
- symptoms of serotonin syndrome: fever, sweating, increased heart rate, uncontrollable diarrhoea, muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER TAKING MIRTAZAPINE GH

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Mirtazapine GH or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

PRODUCT DESCRIPTION

What it looks like

Mirtazapine GH comes in two types of tablets:

Mirtazapine GH 30mg – beige, oval tablets with a score notch on one side.

Mirtazapine GH 45mg – white, circular tablets.

Available in blisters of 30 tablets.

Ingredients

Active ingredients:

- Mirtazapine GH 30mg – 30mg mirtazapine
- Mirtazapine GH 45mg – 45mg mirtazapine.

Inactive ingredients:

- lactose
- maize starch
- hydroxypropylcellulose
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 8000.

Mirtazapine GH 30mg tablets also contain:

- iron oxide red CI77491
- iron oxide yellow CI77492
- iron oxide black CI77499.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Mirtazapine GH is supplied in Australia by:

Generic Health Pty Ltd

Suite 1. 1175 Toorak Road.

Camberwell VIC 3124

This leaflet was prepared in December 2012

Australian Register Numbers

30mg tablets: AUST R 191019

45mg tablets: AUST R 191020