

PATIENT INFORMATION LEAFLET

MIRTAZAPINE 30mg TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- **Keep this leaflet. You may need to read it again.**
- **If you have further questions, please ask your doctor or your pharmacist.**
- **This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.**

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1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

Mirtazapine 30mg Tablets contain the active substance, mirtazapine.

Mirtazapine is one of a group of medicines called antidepressants. Depression is linked to a shortage of substances which carry messages in the brain (including serotonin and noradrenaline). Mirtazapine helps to relieve the shortage of these 'brain messages'. Common signs of depression include feelings of worthlessness or deep sadness; difficulty with everyday tasks; sleeping too much or not being able to sleep; feeling anxious; and changes in appetite.

It may take 2 to 4 weeks before you start to feel better and sleep better. It is important to take your medicine every day and not to stop taking it unless your doctor tells you to. If you do, your symptoms may come back.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE THIS MEDICINE

DO NOT TAKE Mirtazapine 30mg Tablets:

- if you are allergic to mirtazapine or any of the other ingredients of Mirtazapine 30mg Tablets
- if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAOIs)

Warnings and precautions

Use in children and adolescents under 18 years of age

Mirtazapine 30mg Tablets should normally not be used for children and adolescents under 18 years because efficacy was not demonstrated. Patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional (defiant) behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Mirtazapine 30mg Tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine 30mg Tablets 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 Mirtazapine 30mg Tablets. The long-term safety

effects concerning growth, maturation and cognitive and behavioural development of Mirtazapine 30mg Tablets in this age group have not yet been demonstrated. In addition, significant weight gain has been observed in this age category more often when treated with mirtazapine compared with adults.

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 adults aged less than 25 years 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.

Take special care with Mirtazapine 30mg Tablets and tell your doctor if you have or have had:

- epilepsy (seizures or fits)
- liver disease (including jaundice)
- kidney disease
- heart disease
- low blood pressure
- difficulty in passing water (urinating), which may be caused by an enlarged prostate
- an eye disorder called glaucoma or increased pressure in the eye
- diabetes
- psychiatric disorders such as schizophrenia or manic depression, delirium or senile dementia
- an intolerance to some sugars, as this medicine contains lactose

Other medicines and Mirtazapine 30mg Tablets

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

DO NOT TAKE Mirtazapine 30mg Tablets if you are taking:

- other antidepressants known as Monoamine Oxidase Inhibitors (MAOIs) e.g. moclobemide, tranylcypromine and selegiline. Do not take Mirtazapine 30mg Tablets during the two weeks after you have stopped taking MAOIs. Do not take MAOIs until at least 2 weeks after stopping Mirtazapine 30mg Tablets.

Take care when taking Mirtazapine 30mg Tablets with any of the following medicines:

- erythromycin, used to treat bacterial infections
- certain medicines to treat fungal infections, e.g. ketoconazole
- linezolid, used to treat pneumonia
- rifampicin, used to treat tuberculosis
- medicines for treating HIV/AIDS (e.g. HIV-protease inhibitors)

- certain antidepressants, e.g. venlafaxine, L-Tryptophan, lithium and St John's wort (can lead to the development of serotonin syndrome and should be used with caution)
- nefazodone, an antidepressant
- medicines for schizophrenia (antipsychotics) e.g. olanzapine
- medicines for treating anxiety or insomnia e.g. benzodiazepines
- medicines for treating epilepsy (e.g. carbamazepine and phenytoin)
- triptans, used to treat severe headache
- tramadol, a painkiller
- medicines for severe pain, e.g. morphine
- medicines to treat allergies (antihistamines) e.g. cetirizine
- cimetidine, a medicine used for the treatment of indigestion or stomach ulcers
- medicines to prevent blood clotting e.g. warfarin

Mirtazapine 30mg Tablets with food and drink

You may get drowsy if you drink alcohol while you are taking this medicine. It is therefore advisable to avoid drinking any alcohol. You can take Mirtazapine 30mg Tablets with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Make sure your midwife and/or doctor know you are on Mirtazapine 30mg Tablets. When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

Driving and using machines

Antidepressants can affect your concentration or judgement. When you first start taking Mirtazapine 30mg Tablets, make sure your abilities are not affected before you drive or operate machinery.

Mirtazapine 30mg Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE YOUR MEDICINE

The tablets should be swallowed whole without chewing and with plenty of fluid.

Dosage

Adults

The usual starting dose is 15mg or 30mg, taken preferably in the evening. Your doctor may advise you to increase your dose after a few days to the amount that may be best for you.

After 2 to 4 weeks, talk to your doctor about the effect the treatment has had. If you still don't feel well, your doctor may prescribe a higher dose. After another 2 to 4 weeks talk to your doctor again.

If you have the impression that the effect of Mirtazapine 30mg Tablets is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will probably advise you to take Mirtazapine 30mg Tablets as a single dose before you go to bed, as it may help you to sleep. However, your doctor may suggest you split your dose – for example one tablet in the morning, and another in the evening before you go to bed.

Children

Mirtazapine 30mg Tablets are not recommended for use in children or adolescents (under the age of 18).

Elderly people

Mirtazapine 30mg Tablets can be taken by elderly patients, any dose changes will be done, under the close supervision by your doctor.

People with kidney or liver problems

Patients with kidney or liver problems may be given a lower dose of this medicine.

If you take more of your medicine than you should

Call a doctor straight away or go immediately to the nearest casualty department, taking the remaining tablets with you. The most likely signs of overdose are drowsiness, disorientation and increased heart rate.

If you forget to take your medicine

Do not take a double dose to make up for a forgotten dose. Just skip that dose and take your next one at the normal time.

If you stop taking your medicine

Do not suddenly stop taking Mirtazapine 30mg Tablets even if your depression has lifted. If you stop suddenly, you may feel sick, anxious or agitated and have headaches. It is possible that some of your symptoms may come back.

Once you are feeling better, talk to your doctor who will tell you how to reduce the dose gradually. This will usually be about 4 to 6 months after you start feeling better.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mirtazapine 30mg Tablets can have side effects although not everybody gets them. Some side effects are more likely to occur than others. The possible side effects of mirtazapine are listed below.

STOP taking Mirtazapine 30mg Tablets and tell your doctor immediately if you experience any of the following side effects:

- an allergic reaction - signs of an allergic reaction are swelling of the lips, face and tongue; difficulty breathing; skin rash, itching, feeling faint
- severe blistering or peeling of the skin
- skin and/or whites of the eyes start turning yellow, this may suggest a liver problem (jaundice)
- fits (seizures or convulsions)
- thoughts of harming or killing yourself
- serotonin syndrome - symptoms include fever, sweating, increased heart rate, diarrhoea, muscle twitching, shivering, overactive reflexes, restlessness, mood changes and unconsciousness
- signs of infection such as fever, chills, sore throat, mouth ulcer or stomach upset - may be caused by a change in blood cell types (e.g. red blood cells, white blood cells & platelets) in your body. If you have these symptoms, your doctor will arrange a blood test to check.
- mania (feeling elated or emotionally 'high')
- pancreatitis (inflammation of the pancreas) – symptoms include severe upper abdominal pain often with nausea and vomiting

The following events are less serious but you may wish to discuss them with your doctor or pharmacist if they become troublesome or last a long time.

Very common (affects more than 1 user in 10)

- increase in appetite and weight gain
- drowsiness or sleepiness during the first few weeks of treatment
- headache
- dry mouth

Common (affects 1 to 10 users in 100)

- feeling tired
- dizziness
- shakiness or tremor
- nausea (feeling sick)
- diarrhoea
- vomiting (being sick)
- feeling dizzy or faint especially when you stand up quickly
- swollen ankles caused by fluid retention (oedema)
- sleeping problems (insomnia)
- feeling anxious
- confusion
- abnormal dreams
- back pain
- pain in your joints or muscles
- rash or skin eruptions

Uncommon (affects 1 to 10 users in 1,000)

- restless legs
- numbness or ‘pins and needles’ (paraesthesia)
- fainting
- feeling of numbness in the mouth
- urge to move
- feeling agitated
- nightmares, wild dreams or hallucinations
- low blood pressure

Rare (affects 1 to 10 users in 10,000)

- muscle twitching or contractions

Not known (cannot be estimated from the available data)

- low level of sodium in the blood (hyponatraemia)
- difficulty passing urine
- swelling in the mouth
- abnormal sensation in the mouth

In children under 18 years the following adverse events were observed commonly in clinical trials:

- significant weight gain
- nettle rash or hives
- increased triglycerides in your blood (released when food is digested)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING YOUR MEDICINE

Do not use after the expiry date stated on the foil and carton.

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Store in the original package. Keep the blister in the outer carton.

If your doctor tells you to stop treatment, return any left over to the pharmacist.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Mirtazapine 30mg Tablets contain

Each film-coated tablet contains 30mg of the active substance mirtazapine. The other ingredients are lactose monohydrate, pregelatinised maize starch, anhydrous colloidal silica, croscarmellose sodium, magnesium stearate, hypromellose, macrogol 8000, titanium dioxide (E171), yellow iron oxide (E172) and red iron oxide (E172).

What Mirtazapine 30mg Tablets look like and contents of the pack

Mirtazapine 30mg Tablets are brownish, oval, biconvex, film-coated tablets, scored on both sides and marked with I on one side.

The tablets are supplied in blister packs of 28 film-coated tablets.

Marketing Authorisation Holder

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

Manufacturer responsible for batch release

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Distributor

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Product Licence Number: PL 06453/0061

This leaflet was revised in October 2013.