Mirtazapine 30mg tablets

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

1. What Mirtazapine tablets are and what they are used for
2. What you need to know before you take Mirtazapine tablets
3. How to take Mirtazapine tablets
4. Possible side effects
5. How to store Mirtazapine tablets
6. Contents of the pack and other information

What Mirtazapine tablets contain
• The active substance is mirtazapine. Mirtazapine 30mg film-coated tablets contain mirtazapine per film-coated tablets.
• The other ingredients are lactose monohydrate, pregelatinised maize starch anhydrous colloidal silica, crosscarmellose sodium and magnesium stearate.
• Tablet coating: hypromellose, macrogol 8000, titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172) and talc.

Mirtazapine tablets look like and contents of the pack
Mirtazapine 30mg tablets are film-coated tablets. Brownish, scored on both sides, oval, biconvex, film-coated tablets. Marked with “I” on one side. The tablets can be divided into equal halves. Pack size is 28 tablets.

Marketing Authorisation Holder and Manufacturer
Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in August 2015

What is in this leaflet:
• Important information for you.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Mirtazapine tablets
Children and adolescents
Mirtazapine should normally not be used for children and adolescents under 18 years because efficacy has not been demonstrated. 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 Mirtazapine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine 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. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Mirtazapine 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
If you are depressed 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 adolescents under 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, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Also take special care with Mirtazapine tablets if you
• have, or have ever had one of the following conditions. Tell your doctor about these conditions before taking Mirtazapine, if not done previously - seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Mirtazapine and contact your doctor immediately.

Mirtazapine 30mg tablet leaflet - UK

296x210 Leaflet Reel Fed Bi Fold Profile (BST)
Actavis BST - Packing Technical

BSTCutterGuideReq@actavis.com

Dimensions:

Component:

Date Sent:

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Mirtazapine Tablets

JDE No.:

Take care when

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- Hypericum perforatum

- SSRIs, venlafaxine and L-tryptophan

- MAO inhibitors

- MAO inhibitors (a herbal remedy for depression).

- combinations (SSRIs) may increase the risk of a serious

- pregnant or are planning to have a baby, ask your

- limited experience with mirtazapine administration to pregnant women does not indicate an increased

- your dose again.

- a combination of symptoms such as inexplicable

- St. Johns Wort

- you may need to adjust your dose of

- if you are using this medicine. In case of combination

- medicines for

- medicines for

- medicines for bacterial infections such as erythromycin,

- medicines for severe pain such as morphine.

- in combination with these medicines, mirtazapine can increase the drowsiness caused by these medicines.

- medicines for infections, medicines for bacterial infections such as erythromycin, medicines for fungal infections such as ketoconazole,

- for Parkinson’s disease).

- when taken during pregnancy,

- before you drive or operate machinery.

- may affect up to 1 in 100 people):

- feeling elated or emotionally high’ (mania).

- severe upper abdominal pain often with nausea and vomiting (pancreatitis)

- used to treat some psychiatric conditions

- tryptans

- medications for bacterial infections such as erythromycin, medicines for fungal infections such as ketoconazole,

- when to take mirtazapine tablets

- may be caused by an

- difficulty in passing water

- eye (glaucoma)

- manic depression

- schizophrenia

- liver disease

- jaundice

- low blood pressure

- heart disease, or low blood pressure

- schizophrenia. If psychotic symptoms, such as paranoid thoughts become more frequent or severe, contact your doctor straight away

- manic depression (alternating periods of feeling elated/overactivity and depressed mood). If you feel your illness flared or over-

- diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines)

- eye, such as increased pressure in the

- difficulty in passing water (urinating), which may be caused by an enlarged prostate.

- develop signs of infection such as unexplained

- high fever, sore throat and mouth ulcers.

- stop taking mirtazapine tablets and consult your doctor immediately for a blood test.

- rare these symptoms may commonly appear after 4-6 weeks of treatment.

- are an elderly person. You could be more sensitive

- other side-effects of antidepressants.

- medicines and mirtazapine tablets

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

- do not take mirtazapine in combination with:

- monoamine oxidase inhibitors (MAO inhibitors).

- do not take mirtazapine during the two weeks after you have stopped taking MAO inhibitors. If you stop taking mirtazapine, do not take MAO inhibitors during the next two weeks either. Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson’s disease).

- take care when taking mirtazapine in combination with:

- antidepressants such as SSRIs, venlafaxine and L-tryptophan or triptans (used to treat migraine), tramadol (pain killer), irinotecan (an anti-cancer medicine), lithium (used to treat some psychiatric conditions) and St. John’s Wort – Hypericum perforatum preparations (is a herbal remedy for depression).

- in very rare cases mirtazapine alone or the combination of mirtazapine with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.

- the antidepressant nefazodone. It can increase the amount of mirtazapine in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of mirtazapine, or when these medicines are stopped to increase the dose of mirtazapine again.

- medicines to prevent blood clotting such as warfarin. Mirtazapine can increase the effects of warfarin on the blood. Inform your doctor if you are using this medicine. In case of combination it is advised that a doctor monitors your blood carefully.

- mirtazapine tablets with food, drink and alcohol

- You may get drowsy if you drink alcohol while you are taking mirtazapine. You are advised not to drink alcohol.

- You can take mirtazapine with or without food.

- pregnancy and breast-feeding

- If you are pregnant or breast-feeding, tell your doctor about the effects of Mirtazapine tablets. When taken during pregnancy, mirtazapine does not affect the baby. However your doctor may suggest you to split your dose of Mirtazapine – once in the morning and once at night time before you go to bed. The higher dose should be taken before you go to bed. Take your tablets orally. Swallow your prescribed dose of Mirtazapine without chewing, with some water.

- when can you expect to start feeling better

- Usually Mirtazapine will start working after 1 to 2 weeks and after 2 to 4 weeks you may start to feel better.

- It is important that during the first few weeks of the treatment, you talk with your doctor about the effects of Mirtazapine tablets. After 2 weeks you have started taking mirtazapine tablets, talk to your doctor about how this medicine has affected you.

- If you still don’t feel better, your doctor may prescribe a higher dose. In that case, talk to your doctor again after another 2 to 4 weeks. Usually you will need to take Mirtazapine tablets until your symptoms of depression have disappeared.

- if you take more mirtazapine tablets than you should

- If you or someone else have taken too many Mirtazapine tablets, call a doctor straight away.

- The most likely signs of an overdose of Mirtazapine (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate.

- if you forget to take mirtazapine tablets

- If you are supposed to take your dose once a day:

- If you have forgotten to take your dose of Mirtazapine, do not take the missed dose. Just skip it. Take your next dose at the normal time.

- If you are supposed to take your dose twice a day:

- If you have forgotten to take your morning dose, simply take it together with your evening dose.

- if you have forgotten to take your evening dose, do not take it with the next morning dose. Just skip it and continue with your normal morning and evening doses.

- if you have forgotten to take both doses, do not attempt to make up for the missed doses. Skip both doses and continue the next day with your normal morning and evening doses.

- if you stop taking mirtazapine tablets

- Only stop taking Mirtazapine in consultation with your doctor.

- If you stop too early, your depression might come back. Once you are feeling better, talk to your doctor. Your doctor will decide when treatment can be stopped.

- Do not suddenly stop taking Mirtazapine, even when your depression has lifted. If you suddenly stop taking Mirtazapine you may feel sick, dizzy, agitated or anxious, and have headaches. These symptoms can be avoided by stopping gradually. Your doctor will tell you how to decrease the dose gradually.

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

- possible side effects

- Like all medicines, this medicine can cause side effects, although not everybody gets them.

- stop taking mirtazapine tablets and tell your doctor immediately if you experience any of the following side effects:

- uncommon (may affect up to 1 in 100 people):

- feeling elated or emotionally high’ (mania).

- rare (may affect up to 1 in 1,000 people):

- yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice).

- severe upper abdominal pain often with nausea and vomiting (pancreatitis)

- not known (frequency cannot be estimated from the available data):

- Signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (angulocutaneous).

- Epileptic attack (convulsions).

- A combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness. In very rare cases this can be signs of serotonin syndrome.

- Thoughts of harming or killing yourself – contact your doctor or go to a hospital straight away.

- A skin reaction known as erythema multiforme (itchy reddish purple patches on the skin, especially on the palms of the hands or soles of the feet, ‘hives-like’ raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals, which may be accompanied by fever and tenderness).

- Severe rash, blistering (bullous dermatitis), peeling or other effects on the skin, eyes, mouth or genitals, itching or high temperature (symptoms of severe skin reactions called Stevens-Johnson syndrome or toxic epidermal necrolysis).