Mirtazapine 15mg and 45mg film-coated tablets

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Mirtazapine

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 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, 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.

What is in this leaflet:
1. What Mirtazapine is and what it is used for
2. What you need to know before you take Mirtazapine
3. How to take Mirtazapine
4. Possible side effects
5. How to store Mirtazapine
6. Contents of the pack and other information

What Mirtazapine is and what it is used for
Mirtazapine is one of a group of medicines called antidepressants. Mirtazapine is used to treat depressive illness.

What you need to know before you take Mirtazapine
Do not take Mirtazapine if you are
• allergic to mirtazapine or any of the other ingredients of this medicine (listed in section 6).
• pregnant or breast-feeding.

How to take Mirtazapine
• Swallow the tablets whole with a little water.
• Do not cut, break or chew the tablets.

Possible side effects
• Common effects appear in more than 1 in 10 people
• Uncommon effects appear in between 1 in 10 and 1 in 100 people
• Rare effects appear in less than 1 in 100 people

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.

Common side effects
• Dizziness
• Sleepiness
• Low blood pressure
• Feeling distressed

Uncommon side effects
• Muscle pain or weakness, or swelling caused by abnormal muscle breakdown sometimes accompanied with dark coloured urine (rhabdomyolysis).

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people):
• increase in appetite and weight gain
• dry mouth

Common (may affect up to 1 in 10 people):
• lethargy
• dizziness
• shakiness or tremor
• nausea
• diarrhoea
• vomiting
• constipation
• rash or skin eruptions (rash)
• pain in your joints (arthralgia) or muscles (myalgia)
• back pain
• feeling dizzy or faint when you stand up suddenly (orthostatic hypotension)
• swelling (typicallly in ankles or feet) caused by fluid retention (oedema)
• tiredness
• vivid dreams
• confusion
• feeling anxious
• sleeping problems

In children under 18 years the following side effects have been commonly observed:
• significant weight gain
• hives
• increased blood triglycerides

Uncommon (may affect up to 1 in 100 people):
• abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paresthesia)
• restless legs
• fainting (syncope)
• sensations of numbness in the mouth (oral hypoaesthesia)
• low blood pressure
• nightmares
• feeling agitated
• hallucinations
• urge to move
• muscle twitching or contractions (myoclonus)

Rare (may affect up to 1 in 1000 people):
• muscle twitching or contractions (myoclonus)
• feeling aggressive

Not known (frequency cannot be estimated from the available data):
• abnormal sensations in the mouth (oral paresthesia)
• swelling in the mouth (mouth oedema)
• hyponatraemia
• inappropriate anti-diuretic hormone secretion
• increased salivation
• blurred vision (diphractia)
• sleepwalking
• difficulty passing urine
• changes in blood enzymes (shown in blood tests).

Contents of the pack and other information
What Mirtazapine contains
• The active substance is mirtazapine.

Mirtazapine 15mg film-coated tablets contain 15mg mirtazapine per film-coated tablet.
Mirtazapine 45mg film-coated tablets contain 45mg mirtazapine per film-coated tablet.

• The other ingredients are:

Tablet core: lactose monohydrate, pregelatinised maize starch, croscarmellose sodium, magnesium stearate. Tablet coating: hypromellose, macrogol 8000, titanium dioxide (E171) talc. Coating of Mirtazapine 15mg film-coated tablets also contains yellow iron oxide (E172) and red iron oxide (E172).

What Mirtazapine looks like and contents of the pack
Mirtazapine 15mg and 45mg are film-coated tablets. 15mg tablets: Yellow, scored on both sides, oval, biconvex, film-coated tablets. Marked with “T” on one side. The tablet can be divided into equal halves 45mg tablets: White, oval, biconvex, film-coated tablets. Marked with “H” on one side.

Pack sizes
28 tablets in blister.

Marketing Authorisation Holder
Actavis Group PTC ehf, Reykjavikurvegi 76-78, IS-220 Hafnarfjordur, Iceland

Manufacturer
Actavis, Barnstaple, EX32 8NS, UK

This leaflet was last revised in June 2015
• take special care with Mirtazapine if you have, or have ever had one of the following conditions.
• this medicine can cause side effects, although not everybody gets them.
• Please, see the leaflet for Blisters.
• If you stop taking Mirtazapine
• 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.