Buspirone All Strengths PIL UK

Buspirone 5mg and 10mg tablets

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

1 What Buspirone tablets are and what they are used for

Buspirone tablets belong to a group of medicines called anxiolytics. These medicines work on the central nervous system, altering levels of chemicals in the brain.

Buspirone tablets may be used for:

- short term management of anxiety disorders
- relief of symptoms of anxiety with or without symptoms of depression.

2 What you need to know before you take Buspirone tablets

Do not take Buspirone tablets if you:

- are allergic to buspirone hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- are pregnant or breast-feeding.
- have epilepsy.
- have severely impaired liver or kidney function.

Warnings and precautions

Talk to your doctor or pharmacist before you take Buspirone tablets if you:

- have liver or kidney function in the past.
- have been prescribed a benzodiazepine e.g. nitrazepam or temazepam or another common sedative or hypnotic medicine.
- have had severely impaired liver or kidney function.
- have had drug dependence

Other medicines and Buspirone tablets

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

- monoamine-oxidase inhibitors (MAOIs) such as phenelzine and tranylcypromine (for depression)
- St. John’s Wort, nefazodone and L-tryptophan, fluvoxamine, trazodone (for depression)
- selective serotonin re-uptake inhibitors (SSRIs) e.g. fluoxetine and paroxetine (for depression)
- haloperidol and lithium (for mental illness)
- calcium channel blockers such as diltiazem and verapamil (to treat high blood pressure)
- sympathic (to treat tuberculosis)
- triptan drugs e.g. sumatriptan (to treat migraine)
- tramadol, (a painkiller)
- baclofen (a muscle relaxant)
- levo-adrenaline (to manage drug withdrawal)
- nilbutone (to treat nausea and vomiting)
- antihaistamines (to treat allergic reactions)
- erythromycin, tetracaine and linzolide (to treat infections)
- benzodiazepines e.g. nitrazepam or temazepam or another common sedative or hypnotic medicine
- diltiazem (to treat angina)
- digoxin (to treat heart failure)
- phenobarbital, phenytoin, carbamazepine (to treat epilepsy)
- cimetidine (to treat stomach ulcers)
- diazepam (to treat anxiety)
- warfarin (to treat blood clots)

Buspirone tablets with food or drink

Talk to your doctor before eating or drinking products containing grapefruit juice, whilst taking Buspirone tablets. You should not drink alcohol whilst taking Buspirone tablets.

Pregnancy and breast-feeding

Do not take Buspirone tablets if you are pregnant or are breast-feeding.

Driving and using machines

Buspirone tablets may make you feel drowsy or dizzy. Make sure you are not affected before you drive or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Continued top of next column

AAAJ0902
Sugar intolerance
If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicine, as it contains a sugar called lactose.

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

Swallow the tablets with water, at the same time each day. Buspirone should be taken consistently with or without food. However, the medicine is taken on the day one should be continued thereafter.

Doses:
Adults (including the elderly) The recommended starting dose is 5mg two to three times a day, which may be increased every two to three days. The longest duration you will be maintained on is 15mg to 30mg a day in divided doses. The maximum daily dosage should not exceed 60mg per day.

Children: Not recommended.

If you have impaired liver or kidney function, your doctor may prescribe you a lower dose.

If you take more than you should If you (or someone else) swallow a lot of the tablets at the same time, or if you think a child has swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, headache, dizziness, drowsiness, ringing or buzzing in the ears, restlessness, restlessness of the pupils, stomach problems, slow heart beat, low blood pressure, fits and extrapyramidal symptoms (difficulty in speaking or swallowing, loss of balance control, muscle rigidity, difficulty controlling movement/jerky movements, disorder affecting posture (muscle spasm of neck, shoulders and body), fainting or passing out, total or partial memory loss, lack of muscle control, co-ordination, difficulty in controlling movements, tremor, stiffness and shuffling, restless leg syndrome, restlessness, difficulty passing water, over production of breast milk.

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

How to store Buspirone tablets
Keep out of the sight and reach of children. Do not store above 25°C. Store in the original container.

Do not use Buspirone tablets after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

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.

Contents of the pack and other information
What Buspirone tablets contain
The active substance is buspirone hydrochloride. Each tablet contains either 5mg or 10mg of the active substance.

The other ingredients are lactose monohydrate, magnesium stearate, purified talc, polyvidone K-25 and potato starch.

What Buspirone tablets look like and contents of the pack
Buspirone tablets are white, uncoated, flat bevilled edge tablets. Pack size is 30.

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

This leaflet was last revised in June 2016

If you would like a leaflet with larger text, please contact 01271 385257.