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 the:
- 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 taking Buspirone tablets if you have:
- had impaired liver or kidney function in the past
- been prescribed benzodiazepines e.g. nitrazepam or temazepam or another common sedative or hypnotic medicine. You should be gradually withdrawn from these medicines before taking Buspirone tablets
- depression or other conditions that are treated with antidepressants. The use of these medicines together with buspirone can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Buspirone tablets”)
- acute narrow-angle glaucoma
- myasthenia gravis, a disorder characterised by muscle weakness, difficulty chewing or swallowing and slurred speech
- 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, tranylcypromine (for depression)
- St. John’s Wort, melatonin, L-tryptophan, fluoxetine, trazodone (for depression)
- selective serotonin re-uptake inhibitors (SSRIs) e.g. fluoxetine, paroxetine (for depression)
- serotonin noradrenaline re-uptake inhibitors (SNRIs) e.g. duloxetine, venlafaxine
- tricyclic antidepressants e.g. amitriptyline, clomipramine
- haloperidol, lithium (for mental illness)
- calcium channel blockers such as diltiazem, verapamil (to treat high blood pressure)
- amitriptyline (to treat epilepsy)
- triptan drugs e.g. sumatriptan (to treat migraine)
- tramadol (a painkiller)
- blood thinners
- 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)
- phenytoin (to treat stomach ulcers)
- diazepam (to treat anxiety)
- warfarin (to treat blood clots).

Buspirone tablets with food, drink and alcohol
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
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Buspirone should not be given to a pregnant or breast-feeding woman as it is unknown if it affects the growth of the unborn or breast-fed baby. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
Buspirone tablets may make you feel drowsy or dizzy. Make sure you are aware of how it affects you.

- 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 safely.
- If 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
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and

No changes are permitted by any 3rd party other than added notes and mark ups for required changes.
Buspirone tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugar, contact your doctor before taking this medicinal product.

3 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 tablets should be taken consistently with or without food.

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

Use in children and adolescents
Buspirone tablets are not recommended for use in children or adolescents under the age of 18.

Patients with liver or kidney problems
Your doctor may recommend a lower dose if you have liver or kidney problems.

If you take more Buspirone tablets than you should
If you (or someone else) swallow too many tablets at the same time, or if you think a child has swallowed any, speak to your doctor or local hospital immediately.

If you forget to take Buspirone tablets
Do not take a double dose to make up for a forgotten dose.

If you stop taking Buspirone tablets
Continue with buspirone until your doctor tells you to stop.

4 Possible side effects
All medicines can cause side effects, although not everybody gets them.

Stop taking Buspirone tablets and contact your doctor immediately if you have:
- Serotonin syndrome: feeling confused, feeling restless, sweating, shivering, incontinence (farting or passing wind), slurred speech, muscle rigidity, tremor, confusion, hallucinations, violent behavior, vision changes, unusual thoughts or ideas, increased sensitivity to light, fever, blurred vision, confusion.
- Allergic reaction: itching, redness, swelling of the face, lips, throat or tongue, allergic conditions affecting the skin, worsening of symptoms, difficulty breathing, skin rash, hives, swelling of the mouth, throat, or face, swelling of the tongue, hoarseness, swelling of the voice box, difficulty breathing.
- Psychosis and hallucinations
- Fits or seizures
- Restricted vision
- Feeling or passing out

The side effects above are very rare in people taking Buspirone tablets (may affect up to 1 in 10,000 people).

Other side effects:
Very common:
- Dizziness, headache, sleepiness

Common:
- Nervousness, difficulty in sleeping, disturbance in attention, depression, confusion, state changes, sleeping problems, anxiety, excitement, pins and needles, tingling, blurred vision, abnormal coordination, tremors, low blood pressure, restlessness, fast or irregular heartbeat, muscle spasm, unusual gum problems, unusual gum bleeding, drowsiness, ringing or buzzing in the ears, racing heart (abnormally fast heartbeat), chest pain, blocked nose, sore throat, feeling and being sick, stomach pain, dry mouth, diarrhea, constipation, cold sweats, rash, pain in the muscles, tendons, ligaments and bone, mental and physical tiredness

Rare:
- May affect up to 1 in 10 people
- Bruising, itchy skin rash caused by allergic reaction - pain or red irregular raised patches with severe itching (hives)

Very rare:
- May affect up to 1 in 10,000 people
- Feeling that the mind is separated from the body, effect on your balance, extrapyramidal disorder (tremor, slurred speech, restlessness (akathisia), dystonia (affecting posture - muscle spasm of the neck, shoulder or body), anxiety, distress, muscle rigidity, difficulty controlling movement/jerky movements, disorder affecting posture (muscle spasm of neck, shoulder and body), total or partial memory loss, lack of muscle control, co-ordination, difficulty in controlling movements, tremors, stiffness and shuffling, restless leg syndrome, restlessness, difficulty passing waters, over production of breast milk.

5 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 NHR A Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for NHR A Yellow Card in the Google Play or Apple App Store.

6 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-29 and 5-iodo starch.

What Buspirone tablets look like and contents of the pack
Buspirone 5mg Tablets are white, uncoated, flat bevelled edge with '55' on one side and plain on the other. Buspirone 10mg Tablets are white, uncoated, flat bevelled edge with '10' on one side and a score line on the other.

Pack size is 30.

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

This leaflet was last revised in April 2021.

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