

PATIENT INFORMATION LEAFLET

Buspar® 5mg Tablets (buspirone hydrochloride)

Your medicine is available using the name Buspar 5mg Tablets, but will be referred to as Buspar throughout this leaflet. Buspar 10mg Tablets are also available.

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Buspar is and what it is used for
2. Before you take Buspar
3. How to take Buspar
4. Possible side effects
5. How to store Buspar
6. Further information

1. What Buspar is and what it is used for

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

Buspar may be used for the:

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

2. Before you take Buspar

Do not take Buspar and tell your doctor if you:

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

Check with your doctor or pharmacist before taking Buspar if you have:

- had impaired **liver** or **kidney** function in the past.
- been prescribed a **benzodiazepine** e.g. nitrazepam or temazepam or another common **sedative** or **hypnotic** medicine. You should be gradually withdrawn from these medicines before taking Buspar.

- **acute narrow-angle glaucoma**.
- **myasthenia gravis**, a disorder characterised by muscle weakness, difficulty chewing or swallowing and slurred speech.
- or have had **drug dependence**.

Taking other medicines

Please **tell your doctor or pharmacist** if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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)
- rifampicin (to treat tuberculosis)
- triptan drugs e.g. sumatriptan (to treat migraine)
- tramadol (a painkiller)
- baclofen (a muscle relaxant)
- lofexidine (to manage drug withdrawal)
- nabilone (to treat nausea and vomiting)
- antihistamines (to treat allergic reactions)
- erythromycin, itraconazole and linezolid (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)

Pregnancy and breast-feeding

Do not take Buspar if you are pregnant or are breast-feeding. Talk to your doctor before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Buspar

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

3. How to take Buspar

Always take Buspar tablets exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

Taking Buspar with food or drink

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

Swallow the tablets **with water**, at the same time each day. Buspar 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 starting dose is 5mg two to three 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 up to a maximum dose of 45mg a day in divided doses.

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, restriction of the pupils, stomach problems, slow heart beat, low blood pressure, fits and extrapyramidal symptoms (difficulty in speaking or swallowing, loss of balance control, mask-like face, shuffling walk, stiffness of arms and legs, trembling or shaking of hands or fingers).

If you forget to take the tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking the tablets

Talk to your doctor before you stop taking the tablets and follow their advice.

4. Possible side effects

Like all medicines, Buspar can cause side effects although not everybody gets them. Please tell your doctor or pharmacist if you notice any of the following effects, they get worse or if you notice any not listed.

Stop taking Buspar and contact your doctor

immediately if you are taking selective serotonin re-uptake inhibitors (SSRIs) e.g. fluoxetine and paroxetine and have: **Serotonin syndrome**, (feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat).

Tell your doctor if you notice any of the following side effects:

- **Psychiatric disorders:** nervousness, insomnia, problems concentrating, depression, confusion, problems sleeping, anger
- **Nervous system:** dizziness, headache, sleepiness, drowsiness, blurred vision, tingling or pins and needles, co-ordination problems, involuntary shakiness, ringing in the ears, fits, tunnel vision, extrapyramidal disorder (tremor, slurred speech, akathisia, dystonia, anxiety, distress), muscle rigidity, with circular jerky movements, difficulty controlling movement/jerky movements, muscle spasm of neck, shoulders and body affecting posture, fainting or passing out, memory loss, Lack of muscle control or co-ordination, difficulty in controlling movements, tremor, stiffness and shuffling, restlessness, restless leg syndrome
- **Cardiac disorders:** racing heart beat, chest pain
- **Respiratory, thoracic and mediastinal disorders:** blocked nose, sore throat
- **Gastrointestinal disorders:** feeling or being sick, stomach pain, dry mouth, diarrhoea, constipation
- **Skin and subcutaneous tissue disorders:** cold sweats, rash, bruising
- **Musculoskeletal and connective tissue disorders:** pain in the muscles, tendons, ligaments and bone
- **Renal and urinary disorders:** difficulty passing water
- **Reproductive system and breast disorders:** over production of breast milk
- **General disorders and administration site conditions:** tiredness

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.

5. How to store Buspar

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (Exp) which is marked on the carton and blister strips. This refers to the last day of that month.

If your tablets appear discoloured, or show any other sign of deterioration, take them to your pharmacist who will advise you.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Further information

What Buspar contains

The active substance is buspirone hydrochloride.

The other ingredients are lactose anhydrous, magnesium stearate, microcrystalline cellulose, silicon dioxide colloidal and sodium starch glycolate.

What Buspar looks like and contents of the pack

Buspar tablets are white, rounded, rectangular tablets marked '5' on one side and plain on the reverse.

Buspar is available in blister packs of 60 and 90 tablets.

Manufactured by: Bristol-Myers Squibb, La Goualle, BP No. 6, 19250-Meymac, France.

Your medicine is procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: Landmark Pharma Ltd., 7 Regents drive, Prudhoe, Northumberland, NE42 6PX.

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PATIENT INFORMATION LEAFLET

Buspirone Hydrochloride 5mg Tablets

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In this leaflet:

1. What Buspirone Hydrochloride is and what it is used for
2. Before you take Buspirone Hydrochloride
3. How to take Buspirone Hydrochloride
4. Possible side effects
5. How to store Buspirone Hydrochloride
6. Further information

1. What Buspirone Hydrochloride is and what it is used for

Buspirone Hydrochloride belong to a group of medicines called anxiolytics. These medicines work on the central nervous system, altering levels of chemicals in the brain. Buspirone Hydrochloride may be used for the:

- short term management of anxiety disorders
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2. Before you take Buspirone Hydrochloride

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- have **epilepsy**.
- have **severely** impaired **liver** or **kidney** function.

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- been prescribed a **benzodiazepine** e.g. nitrazepam or temazepam or another common **sedative** or **hypnotic** medicine. You should be gradually withdrawn from these medicines before taking Buspirone Hydrochloride.
- **acute narrow-angle glaucoma**.
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