

Package leaflet: Information for the patient

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

1. What Buspirone is and what it is used for

Buspirone contains the active ingredient buspirone hydrochloride. Buspirone belongs to a group of medicines called azapirones, used to treat anxiety. These medicines work on the central nervous system, altering levels of chemicals in the brain which can help make you feel less anxious. It should only be taken for a short time to relieve anxiety.

2. What you need to know before you take Buspirone

Do not take Buspirone:

- if you are allergic to buspirone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have severe liver or kidney problems
- if you have consumed high quantities of alcohol, hypnotics, pain killers or antipsychotic drugs (for mental illness) in the last few days
- if you have epilepsy (suffer from fits)

Warning and precautions

Talk to your doctor or pharmacist before taking Buspirone:

- if you have been prescribed a benzodiazepine e.g. nitrazepam, temazepam or another common sedative or hypnotic medicine (which may make you feel sleepy). You should be gradually withdrawn from these medicines before taking Buspirone
- if you suffer from high pressure in the eye (glaucoma)
- if you have a condition which causes your muscles to become weak and tire easily (myasthenia gravis)
- if you suffer from addiction to drugs
- if you suffer from liver or kidney problems or had them in the past.
- if you are suffering from depression and not feeling anxious, buspirone should not be used alone to treat depression.

- if you have 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”).

Other medicines and Buspirone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may increase the side effects of buspirone and may sometimes cause very serious reactions. Do not take any other medicines whilst taking buspirone without first talking to your doctor, especially:

- Medicines known as monoamine oxidase inhibitors (MAOIs) to treat depression, such as phenelzine or tranylcypromine should not be taken with buspirone
- Antidepressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with buspirone and you may experience symptoms such as involuntary rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- Other medicines to treat anxiety or depression to help you sleep e.g. nefazodone
- Antibiotics such as erythromycin, rifampicin, linezolid
- Anti-fungal medicine such as itraconazole or ketoconazole
- Certain medicines to treat for HIV infection such as ritonavir, saquinavir, indinavir.
- Medicine to treat anxiety including those containing benzodiazepine e.g. diazepam
- Calcium channel blocker medicines used to treat heart conditions e.g. diltiazem, verapamil.
- Medicines used to treat depression, such as selective serotonin re-uptake inhibitors (e.g. fluoxetine, paroxetine, fluvoxamine), St John’s Wort, trazodone and L-tryptophan
- Medicines for mental illness such as haloperidol and lithium
- Medicines used for migraines called triptans such as sumatriptan
- Tramadol (painkiller)
- Baclofen (a muscle relaxant)
- Digoxin which is used to treat heart conditions,
- Medicines used for epilepsy such as carbamazepine, phenytoin and phenobarbital
- Cimetidine- used to treat certain conditions caused by too much acid being produced in the stomach
- Warfarin- medicine used to prevent blood clots
- Antihistamines (used to treat allergic reactions)
- Nabilone (used to treat nausea and vomiting)
- Lofexidine (use to aid drug withdrawal)

Buspirone with food, drink and alcohol

Do not take Buspirone with large quantities of grapefruit juice as this may increase the effect of your medicine causing side effects. **Do not** drink alcohol while taking Buspirone.

Buspirone can be taken before, during or after food but make sure you take it the same way each day.

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 mother as it is not known if it affects the growth of the unborn or breast-fed baby. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or operate machinery until you know that Buspirone does not reduce your reaction time by making you sleepy, dizzy or less alert.

You are more likely to suffer these side effects at the start of treatment or when your dose is changed. Make sure you are not affected before you drive or operate machinery.

This 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 and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine
 - 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 whilst taking this medicine.

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

3. How to take Buspirone

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

Buspirone can be taken before, during or after food, but make sure you take it the same way each day. These tablets **should not** be chewed. Swallow the tablet with a glass of water.

The dosage will be adjusted to individual requirement.

Adults (including older people) – The recommended starting dose is 5 mg two or three times a day.

After several weeks your doctor may increase your dose depending on how you respond to the tablets. The recommended daily dose is 15 mg to 30 mg, divided up throughout the day.

The recommended maximum daily dose is 60 mg.

Buspirone **should not** be taken for a long time but it may take several weeks before you start to feel better.

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 will prescribe a lower dose if you have liver or kidney problems.

If you take more Buspirone than you should

Contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

Symptoms of overdose include dizziness, headache, ringing or buzzing in the ears, restlessness, slow heartbeat, 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) drowsiness, constriction of the pupil, stomach upset and feeling or being sick.

If you forget to take Buspirone

Take the next dose as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Buspirone

Continue with buspirone until your doctor tells you otherwise. If you are to stop buspirone therapy you must follow your doctor's instructions closely. It is especially important as this type of medicine should not be stopped suddenly. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Stop taking Buspirone tablets and contact your doctor immediately if you experience:

Very rare side effects (affecting fewer than 1 in 10,000 people):

- high fever, agitation, confusion, trembling and abrupt contractions of muscles; these may be signs of a rare condition called serotonin syndrome
- allergic reaction – itching, difficulty breathing or swelling of the face, lips, throat or tongue, allergic conditions (causing itchy and swollen skin)
- severe mental condition in which the person loses contact with reality and is unable to think and judge clearly (psychosis)
- fits or seizures
- restricted vision
- unusual, uncontrollable movements including trembling and shaking which may affect hands, eyes, neck, body
- uncontrollable twitching, jerking or writhing movements

The following side effects have also been reported:

Very common side effects (may affect more than 1 in 10 people)

- dizziness
- headache
- drowsiness

Common side effects (may affect up to 1 in 10 people):

- nervousness
- feeling excited
- inability to sleep or sleep disturbances
- disturbance in attention
- depression
- blurred vision
- confusion
- anger
- tingling or pins and needles,
- abnormal coordination, tremor
- buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus)

- chest pain
- fast heart beat
- blocked nose
- throat pain or soreness
- feeling sick (nausea)
- being sick (vomiting)
- dry mouth
- diarrhoea
- constipation
- abdominal pain
- cold sweat
- rash
- muscle and bone pain
- tiredness

Rare side effects (may affect up to 1 in 1,000 people):

- bruising
- hives

Very rare side effects (may affect up to 1 in 10,000 people):

- seeing, feeling or hearing things that are not there (hallucination)
- change in personality
- mood swings
- uncontrollable muscle spasms affecting the eyes, head, neck and body
- increased tension in muscles and joints
- fainting
- loss of memory
- restless legs, difficulty standing still, lack of coordination, affecting balance and manner of walking
- difficulty passing urine
- secretion of breast milk in men, or in women who are not breastfeeding
- a disorder of the central nervous system (symptoms may include tremor, slurred speech, involuntary movements, spasm in muscle of face, shoulder, neck, trunk and limbs, anxiety and distress)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Buspirone

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

Do not use this medicine after the expiry date which is stated on the label or carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 protect the environment.

6. Contents of the pack and other information

What Buspirone contains

The active substance is 5 mg of buspirone hydrochloride.

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

What Buspirone looks like and contents of the Pack

Your medicine comes as a round white tablet. The tablets are marked 'BR 5' on one side and 'G' on the reverse. Buspirone is available in blister packs or containers of 20, 28, 30, 56, 84, 90, 100, 112, 120 or 168 tablets; or only in blister packs of 180 tablets; or only in containers of 5, 7, 10, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 250 or 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Generics [UK] Ltd, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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