

PACKAGE LEAFLET

Package leaflet: Information for the patient

Buspirone hydrochloride 10 mg Tablets

buspirone hydrochloride

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 effect, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

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

Buspirone hydrochloride contains the active ingredient buspirone hydrochloride. Buspirone hydrochloride 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 anxious. It should only be taken for a short time to relieve anxiety.

2. What you need to know before you take Buspirone hydrochloride

Do not take Buspirone hydrochloride:

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

Warning and precautions

Talk to your doctor or pharmacist before taking Buspirone hydrochloride:

- 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 You should be gradually withdrawn from these medicines before taking Buspirone hydrochloride.
- if you suffer from liver or kidney problems or had them in the past.
- 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 high pressure in the eye (glaucoma).
- if you are suffering from depression and are not feeling anxious, this medicine should not be used alone to treat depression.

Other medicines and Buspirone hydrochloride

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

- Medicines known as monoamine oxidase inhibitors (MAOIs) to treat depression, such as Phenelzine or tranylcypromine should not be taken with Buspirone hydrochloride.
- Other medicines to treat anxiety or depression, or to help you sleep e.g. nefazodone.
- Medicine to treat mental illness (antipsychotics) e.g. haloperidol and lithium.
- Medicine for stomach ulcers e.g. cimetidine.
- Antibiotics such as erythromycin, rifampicin, linezolid.
- Anti-fungal medicine such as itraconazole or ketoconazole.
- Certain antivirals which are used in treatment of HIV disease.
- St John's wort, a herbal remedy.
- 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), trazodone and L-tryptophan.
- Medicines called triptans, which are used for migraines (e.g. 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.
- Antihistamines (used to treat allergic reactions).
- Nabilone (used to treat nausea and vomiting).
- Lofexidine (use to aid drug withdrawal).
- Warfarin which is used to prevent blood clots.

Buspirone hydrochloride with food, drink and alcohol

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

Buspirone hydrochloride 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 hydrochloride **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 hydrochloride 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 hydrochloride contains lactose and sodium

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.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Buspirone hydrochloride

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

The tablet can be divided into equal doses.

Buspirone hydrochloride 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.

Adults (including older people)

The recommended starting dose is 5 mg (half of a 1- mg tablet; the tablet can be divided into equal doses) 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 maximum daily dosage should not exceed 60 mg per day.

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

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

If you take more Buspirone hydrochloride 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, not reacting to light, stomach problems, slow heartbeat, low blood pressure, fits and symptoms such as difficulty in speaking or swallowing, loss of balance control, shuffling walk, stiffness of arms and legs, trembling or shaking of hands or fingers), drowsiness, and feeling or being sick.

If you forget to take Buspirone hydrochloride

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 hydrochloride

Continue taking this medicine until your doctor tells you otherwise. If you are to stop Buspirone hydrochloride 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 hydrochloride tablets and contact your doctor immediately if you experience:

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

- high fever, agitation, confusion, trembling and abrupt contractions of muscles; these may be signs of a condition called serotonin syndrome.
- 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.

Contact your doctor immediately if you notice signs of an allergic reaction: itchy skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

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):

- feeling nervous or excited.
- inability to sleep or sleep disturbance.
- disturbance in attention.
- depression.
- blurred vision.
- confusion.
- anger.
- tingling or pins and needles.
- numbness
- abnormal coordination, tremor.
- buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus).
- chest pain.
- fast heart beat, palpitations.
- blocked nose.
- sore throat.
- throat pain.
- being sick (vomiting).
- feeling sick (nausea).
- dry mouth.
- diarrhoea.

- constipation.
- stomach pain.
- cold sweats.
- Rash.
- muscle, bone or joint pain.
- feeling weak or tired.

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

- bruising.
- itchy skin.
- hives.
- loss of hair.

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 or pharmacist. 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 Buspirone hydrochloride

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 hydrochloride contains

- The active substance is buspirone hydrochloride. Each tablet contains 10 mg of buspirone hydrochloride.

- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica and magnesium stearate. See section 2, 'Buspirone hydrochloride contains lactose and sodium'.

What Buspirone hydrochloride looks like and contents of the pack

Your medicine comes as a white capsule shaped tablet. The tablets are marked 'BR () 10' on one side and 'G' on the reverse.

Buspirone hydrochloride is available in blister packs or containers of 20, 28, 30, 50, 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, 21, 25, 60, 250 or 500 tablets.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

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Manufacturers

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