

Pharma code

Package leaflet: Information for the patient

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

1. What Buspirone hydrochloride tablets are and what they are used for

Buspirone hydrochloride 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 hydrochloride 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 hydrochloride tablets

Do not take Buspirone hydrochloride 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 hydrochloride tablets 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 You should be gradually withdrawn from these medicines before taking Buspirone hydrochloride tablets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 hydrochloride 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 hydrochloride 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, nefazodone, L-tryptophan, fluvoxamine, trazodone (for depression)
- selective serotonin re-uptake inhibitors (SSRIs) e.g. fluoxetine, paroxetine (for depression)
- serotonin norepinephrine 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)
- 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, 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).

Buspirone hydrochloride tablets with food, drink and alcohol

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

Buspirone hydrochloride 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 and
 - 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.

Buspirone hydrochloride tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Buspirone hydrochloride 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 hydrochloride tablets should be taken consistently with or without food.

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The recommended dose is:

Adults (including the elderly)

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

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

If you take more Buspirone hydrochloride 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, 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 Buspirone hydrochloride 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 Buspirone hydrochloride tablets

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 hydrochloride tablets and contact your doctor immediately if you have:

- **Serotonin syndrome:** feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat).
- **Allergic reaction:** itching, difficulty breathing or swelling of the face, lips, throat or tongue, allergic conditions (causing itchy and swollen skin)
- Psychosis and hallucinations
- Fits or seizures
- Restricted vision
- Fainting 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: may affect more than 1 in 10 people

- Dizziness, headache, sleepiness

Common: may affect up to 1 in 10 people

- Nervousness, difficulty in sleeping, disturbance in attention, depression, confused state, sleeping problems, anger, excitement, pins and needles, tingling, blurred vision, abnormal coordination, tremor, ringing or buzzing in the ears, racing heart (abnormally fast heart rhythm), chest pain, blocked nose, sore throat, feeling and being sick, stomach pain, dry mouth, diarrhoea, constipation, cold sweats, rash, pain in the muscles, tendons, ligaments and bone, mental and physical tiredness

Rare: may affect up to 1 in 1,000 people

- Bruising, itchy skin rash caused by allergic reaction-pale 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 ability, extrapyramidal disorder (tremor, slurred speech, restlessness (akathisia), dystonia (affecting posture – muscle spasm of the neck, shoulders or body)), anxiety, distress, muscle rigidity, difficulty controlling movement/jerky movements, disorder affecting posture (muscle spasm of neck, shoulders and body), 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 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 hydrochloride tablets

Keep this medicine out of the sight and reach of children. Do not use Buspirone hydrochloride tablets after the expiry date which is stated on the carton.

The expiry date refers to the last day of that month. Store in the original package.

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 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, colloidal anhydrous silica, microcrystalline cellulose, sodium starch glycolate, and magnesium stearate.

What Buspirone hydrochloride tablets look like and contents of the pack

Buspirone hydrochloride 5 mg Tablets are round white to off-white tablets plain from both sides


Buspirone hydrochloride 10 mg Tablets are round white to off-white tablets plain from both sides

Buspirone Hydrochloride tablets are available in transparent PVC/PVDC/Alu blisters, in packs containing 30 tablets.

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