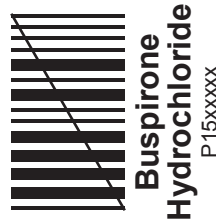


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#### Package leaflet: Information for the user

### Buspirone Hydrochloride 5 mg Tablets 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 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 is and what it is used for
2. What you need to know before your child takes 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 belongs 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
- relief of symptoms of anxiety with or without symptoms of depression.

#### 2. What you need to know before you take Buspirone Hydrochloride

Do not take Buspirone Hydrochloride and tell your doctor if you:

- are **allergic** (hypersensitive) to buspirone hydrochloride or any of the other ingredients in Buspirone Hydrochloride (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 Buspirone Hydrochloride 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 You should be gradually withdrawn from these medicines before taking Buspirone Hydrochloride.
- **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, phenyton, 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 Buspirone Hydrochloride if you are pregnant or are breast-feeding. Talk to your doctor before taking any medicine.

#### Driving and using machines

Buspirone Hydrochloride 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 contains 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

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

#### Taking Buspirone Hydrochloride with food or drink

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

Swallow the tablets **with water**, at the same time each day. Buspirone Hydrochloride 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.

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#### 4. Possible side effects

Like all medicines, Buspirone Hydrochloride can cause side effects although not everybody gets them.

**Stop taking Buspirone Hydrochloride 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:

**Very common (may affect more than 1 in 10 people):**

- dizziness
- headache
- sleepiness, drowsiness

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

- nervousness
- insomnia
- problems concentrating
- depression
- confusion
- problems sleeping
- anger
- blurred vision
- tingling or pins and needles
- co-ordination problems
- involuntary shakiness
- ringing in the ears
- racing heart beat, chest pain
- blocked nose
- sore throat
- feeling or being sick
- stomach pain
- dry mouth
- diarrhoea
- constipation
- cold sweats
- rash
- pain in the muscles, tendons, ligaments and bone
- tiredness

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

- bruising, rash, swelling of face, neck, tongue, mouth or throat

**Very Rare (may affect up to 1 in 10,000 people):**

- 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
- difficulty passing urine
- over production of breast milk

#### Reporting of side effects

If your child gets 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](http://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

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

Store in the original package in order to protect from light.

Do not use Buspirone Hydrochloride after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What Buspirone Hydrochloride contains

The active substance is Buspirone Hydrochloride

##### Buspirone Hydrochloride 5 mg Tablets

Each tablet contains 5 mg Buspirone Hydrochloride

##### Buspirone Hydrochloride 10 mg Tablets

Each tablet contains 10 mg Buspirone Hydrochloride

The other ingredients are:

Lactose monohydrate  
Cellulose, Microcrystalline (Grade -102)  
Sodium Starch Glycolate (Type – A)  
Silica colloidal anhydrous  
Magnesium stearate

##### What Buspirone Hydrochloride looks like and contents of the pack

##### Buspirone Hydrochloride 5 mg Tablets

White to off-white, ovoid rectangular shaped, beveled edged, uncoated tablets debossed “B” and “5” separated by score line on one side and plain on other side.

##### Buspirone Hydrochloride 10 mg Tablets

White to off-white, ovoid rectangular shaped, beveled edged, uncoated tablets debossed “B” and “10” separated by score line on one side and plain on other side.

Pack sizes: 30 tablets.

##### Marketing Authorisation Holder

Milpharm Limited  
Ares Block  
Odyssey Business Park  
West End Road  
Ruislip HA4 6QD  
United Kingdom

##### Manufacturer

APL Swift Services (Malta) Limited  
HF26, Hal Far Industrial Estate, Hal Far,  
Birzebbugia, BBG 3000, Malta

Or

Milpharm Limited  
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Ruislip, HA4 6QD, United Kingdom

Or

Generis Farmacêutica, S.A.,  
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Amadora, Portugal

**This leaflet was last revised in 02/2025.**