

Package leaflet: Information for the patient

Buripal 5 mg tablets

Buripal 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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name] is a medicine that is used for the symptomatic treatment of anxiety states of clinically relevant severity with the following cardinal symptoms: anxiety, agitation, tension.

2. What you need to know before you take [Invented name]

Do not take [Invented name] if you

- are allergic to buspirone or any of the other ingredients of this medicine (listed in section 6)
- have acute angle-closure glaucoma (eye disease)
- have *myasthenia gravis* (severe muscle weakness)
- have any severe liver or kidney disease
- have epilepsy
- have acute intoxication with alcohol, hypnotics, analgesics, or antipsychotic drugs.

Warnings and precautions

Talk to your doctor or pharmacist before taking [Invented name] if you

- have taken a medicine with calming effect on the central nervous system for a long time. Before taking [Invented name], these medicines should be discontinued gradually.
- have a history of kidney or liver disease
- have a history of seizures
- have a history with drug dependence.

Children and adolescents

[Invented name] should not be used in children and adolescents under 18 years of age (see “How to take [Invented name]” below).

Other medicines and [Invented name]

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

It is especially important to tell your doctor if you are taking any of the following:

- Medicines known as monoamine oxidase inhibitors (MAOIs), such as phenelzine or tranylcypromine (to treat depression and Parkinson's disease). You should not take these medicines concomitantly with [Invented name].
- Medicines known as selective serotonin re-uptake inhibitors (SSRIs), such as fluoxetine, fluvoxamine and paroxetine (for depression and other psychiatric disorders)
- Buprenorphine
- Antihypertensives (for high blood pressure)
- Antidiabetics (for diabetes)
- Anticoagulants such as warfarin (for stopping the blood from clotting)
- Contraceptives (for pregnancy prevention)
- Cardiac glycosides such as digoxin (for heart failure)
- Antihistamines (for allergy/hypersensitivity)
- Dexamethasone (for inflammatory and autoimmune conditions, such as rheumatoid arthritis)
- Phenytoin, phenobarbital, carbamazepine (for epilepsy)
- Nefazodone (for depression)
- Erythromycin (for various types of infections caused by bacteria)
- Linezolid (for severe infections caused by gram-positive bacteria)
- Itraconazole (for fungal infections)
- Diltiazem or verapamil (for high blood pressure, angina, heart failure, and as a preventive medication for migraine)
- Triptans (for migraine)
- Tramadol (for severe pain)
- Cimetidine (for heartburn and peptic ulcers)
- Rifampicin (for tuberculosis and other infections)
- Strong CYP3A4 inhibitors (such as ketoconazole or ritonavir)
- Baclofen (for treatment of spasticity)
- Lofexidine (for opioid withdrawal)
- Nabilone (for control of nausea and vomiting)
- Haloperidol (for schizophrenia and for acute psychotic states and delirium)
- Trazodone (for depression)
- Lithium (for manic-depression)
- St. John's wort (for depression)
- L-tryptophan (nutritional supplement)
- Diazepam (for anxiety, sleep disorders, seizures, including epileptic seizures, muscle spasms, restless legs syndrome, alcohol withdrawal, benzodiazepine withdrawal, and Ménière's disease).

A change in dose may need to be considered by your doctor.

[Invented name] with food, drink and alcohol

Alcohol

You should not drink alcohol while taking [Invented name].

Grapefruit juice

You should not eat or drink products containing large quantities of grapefruit juice while taking [Invented name].

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.

Pregnancy

[Invented name] should not be taken during pregnancy unless your doctor has specifically recommended it.

Breast-feeding

Breast-feeding is not recommended during treatment.

Driving and using machines

Do not drive or use any tools or machines until you know how [Invented name] affects you. It cannot be excluded that [Invented name], especially at the beginning of treatment and after a change in dose, affects the capacity of reaction.

[Invented name] contains lactose

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

Other excipients

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

3. How to take [Invented name]

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

Adults (over 18 years of age)

The recommended starting dose is 5 mg three times daily (corresponding to 15 mg buspirone hydrochloride daily).

Your doctor may increase this dose gradually if necessary. The daily dose can be increased to 20-30 mg buspirone hydrochloride daily, divided into several individual doses. A single dose of 30 mg buspirone hydrochloride should not be exceeded. More than 60 mg buspirone hydrochloride per day should not be taken.

Patients with kidney and/or liver problems

These patients might need a lower dose. Your doctor will determine your individual dose.

Use in children and adolescents

[Invented name] should not be used in children and adolescents under 18 years of age.

Method of administration

The tablets should always be taken at the same time of day, either always on an empty stomach or always after a meal. The tablets should be swallowed with some liquid.

Duration of treatment

It may take some time before you start feel better. If the symptoms do not improve within 4-8 weeks, you should talk to your doctor. Your doctor will determine how long you should continue to take [Invented name]. If a long-term medical treatment is necessary, it should be monitored intensively by your doctor and the need to continue treatment should be periodically reassessed.

If you take more [Invented name] than you should

If you have taken too much of the medicine or if, for example, a child has taken the medicine by mistake, contact your doctor or hospital for an assessment of the risk and advice.

Take the medicine pack with you.

The typical symptoms of an overdose include nausea, vomiting, dizziness, fatigue, constriction of the pupils and stomach pains.

If you forget to take [Invented name]

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 possible. However, if it is almost time for your next dose, skip the missed dose and continue as before.

If you stop taking [Invented name]

Continue with [Invented name] until your doctor tells you otherwise. If you need a long-term medical treatment your doctor will monitor your use of this medicine on a regular basis.

If you are to stop [Invented name] therapy, you must follow your doctor's instruction 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 [Invented name] and contact your doctor immediately if you have:

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

- **Serotonin syndrome** (fever, confusion, agitation, 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, tongue or skin).

The following side effects have also been reported:

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

- nonspecific chest pain
- nightmares, drowsiness, sleeplessness, dizziness, nervousness, light-headedness, impaired concentration, restlessness, anger, hostility, confusion, depression
- blurred vision
- ringing or buzzing in the ears (tinnitus)
- sore throat, stuffy nose
- nausea, dry mouth, gastrointestinal symptoms, diarrhoea
- headache, weakness.

Uncommon (may affect up to 1 in 100 people):

- brief episodes of fainting, low or high blood pressure, exceedingly high heart rate/abnormality of heartbeat
- depersonalisation, over-sensitivity to certain frequency ranges of sound, excitement, unpleasant mood (including symptoms such as sadness, irritability, restlessness), urge to move, anxiety, loss of interest, association disturbances, hallucinations, suicidal thoughts, seizures
- numbness, abnormal sensations (e.g., tingling, pricking sensation), loss of coordination, involuntary trembling
- significantly increased breathing frequency, shortness of breath, chest pressure, altered sense of smell
- redness of the eyes, itchy eyes, inflammation of the outermost layer of the eye and the inner surface of the eyelids
- increased appetite, poor appetite, drooling, rectal bleeding, constipation, passing gas (flatulence), irritable colon, vomiting
- lower urinary tract symptoms
- oedema, nettle rash, flushing, tendency to bruising, hair loss, dry skin, eczema, vesicles, facial oedema

- muscle cramps, muscle pain, muscle tension, joint pain
- weight gain, fever, roaring in the head, weight loss, general feeling of being unwell, tiredness, altered taste, sweating, clammy hands
- increased liver enzymes
- menstrual disorders, decreased or increased sexual desire.

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

- disorders in the blood supply to the brain, heart failure, heart attack, dysfunction of the heart muscle, slow resting heart rate
- blood count changes (increased number of certain white blood cells [eosinophilia], decreased number of certain blood cells [leukopenia], decreased number of platelets in the blood [thrombocytopenia])
- mood swings, claustrophobia, cold intolerance, sleepiness which can cause immobility or unconsciousness, slurred speech, psychosis, transient memory gaps
- extrapyramidal symptoms including involuntary movements of the body during or after treatment, involuntary movements of the body, face, mouth, or tongue and stiffness of the body, parkinsonism (e.g., symptoms such as slow movements and trembling), akathisia (e.g., symptoms such as restlessness, being unable to sit still), restless legs syndrome (e.g., symptoms such as burning, itching or tingling in the muscles), slowed reaction time
- eye pain, sensitivity to light, sensation of pressure on the eyes, constricted circular tunnel-like field of vision
- nosebleeds
- inability to control urination, need to get up in the night to urinate
- small haemorrhages of the skin, acne, nail thinning
- muscle weakness
- milk secretion from the breast, breast enlargement in males, thyroid dysfunction
- alcohol abuse, bleeding disorders, loss of voice, hiccups, burning tongue
- absence of menstrual period, pelvic inflammatory disease, abnormal ejaculation, impotence.

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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 carton, blister or bottle. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

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 [Invented name] contains

- The active substance is buspirone hydrochloride.
- 5 mg tablets: Each tablet contains 5 mg buspirone hydrochloride.
- 10 mg tablets: Each tablet contains 10 mg buspirone hydrochloride.

- The other ingredients are microcrystalline cellulose (E460), lactose monohydrate, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate.

What [Invented name] looks like and contents of the pack

5 mg tablets: Round white to off-white tablets plain from both sides with a diameter of approximately 6 mm.

10 mg tablets: Round white to off-white tablets plain from both sides with a diameter of approximately 8 mm.

Pack sizes:

Blister: 20, 30, 50, 60, 90 and 100 tablets.

Plastic bottle with child-resistant closure: 100 and 250 tablets.

Not all package sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in 2024-01-18.