

Buspirone

Buspirone hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using Buspirone.

This leaflet answers some common questions about Buspirone. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Buspirone against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Buspirone is used for

Buspirone 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.

Your doctor may have prescribed Buspirone for another reason.

Ask your doctor if you have any questions about why Buspirone has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you take Buspirone

When you must not take it

Do not take Buspirone if:

- you have ever had an allergy to buspirone or to any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Buspirone if:

- you suffer from acute angle-closure glaucoma (eye disease)
- you suffer from myasthenia gravis (severe muscle weakness)
- you if you suffer from any severe liver or kidney disease
- you suffer from epilepsy
- you suffer from acute intoxication with alcohol, hypnotics, analgesics, or antipsychotic drugs.

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Do not take Buspirone after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist.

Before you start to take it

Tell your doctor if:

- you have taken a medicine with a calming effect on the central

nervous system for a long time. Before taking Buspirone, these medicines should be discontinued gradually.

- you have a history of kidney or liver disease
- you have a history of seizures
- you have a history with drug dependence.
- you are pregnant or plan to become pregnant. Your doctor can discuss with you the risks and benefits involved.
- you are breastfeeding or plan to breastfeed. Breastfeeding is not recommended during treatment.

If you have not told your doctor about any of the above, report them before you take any Buspirone.

Tell your doctor if you have intolerance to lactose.

This medicine contains sugars as lactose.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Buspirone may interfere with each other. These include:

- 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 Buspirone.

- 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)
- 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)

These medicines may be affected by Buspirone, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Buspirone.

How to take Buspirone

Follow all directions given to you by your doctor and pharmacist carefully.

These directions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual starting dose is 5 mg three times daily.

Your doctor may increase this dose gradually if necessary.

How to take it

The tablets are scored and can be divided into equal doses. The whole tablets or, if needed, the divided halves should not be chewed or crushed but swallowed whole with some liquid. The tablets should always be taken at the same time of day, either always on an empty stomach or always after a meal.

How long to take it

Do not stop taking this medicine without first checking with your doctor.

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 Buspirone. 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 forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Buspirone.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include nausea, vomiting, dizziness, fatigue and stomach complaints.

While you are using Buspirone

Things you must do

If you become pregnant, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Buspirone.

Things you must not do

Do not give this medicine to anyone else, even if their condition seems similar to yours.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Alcohol

You should not drink alcohol while taking Buspirone.

Grapefruit juice

You should not eat or drink products containing large quantities of grapefruit juice while taking Buspirone.

Do not drive or use any tools or machines until you know how Buspirone affects you.

It cannot be excluded that Buspirone, especially at the beginning of treatment and after a change in dose, affects the capacity of reaction.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Buspirone

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Some of the side effects listed below are more common at the beginning of treatment and may disappear as treatment continues.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and they worry you:

- nonspecific chest pain
- nightmares, drowsiness, sleeplessness, dizziness, nervousness, light-headedness, impaired concentration, restlessness, agitation, 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.

Tell your doctor immediately if you notice any of the following side effects:

- 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 pain, altered sense of smell

- unusual and uncontrolled movements of the body such as twisting, jerking or writhing movements
- eye pain, sensitivity to light, sensation of pressure on the eyes, constricted circular tunnel-like field of vision.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects.

You may not experience any of them.

After using Buspirone

Storage

- Keep the blister in the outer carton in order to protect from light.
- Store it in a cool dry place where the temperature stays below 25°C. Protect from light.
- Do not store Buspirone or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Buspirone or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Buspirone 5 mg tablets are white or almost white, oval tablets debossed with 'ORN 30' on one side and a score on the other side.

Buspirone 10 mg tablets are white or almost white, oval tablets debossed with 'ORN 31' on one side and a score on the other side.

Buspirone tablets are available in blister packs of 100 tablets.

Ingredients

Buspirone tablets contain 5 mg or 10 mg of buspirone hydrochloride as the active ingredient.

The tablets also contain:

- Lactose monohydrate
- Silica, colloidal anhydrous
- Cellulose, microcrystalline
- Sodium starch glycolate (type A)
- Magnesium stearate

Buspirone tablets does not contain gluten, tartrazine or any other azo dyes.

Sponsor

Buspirone tablets are supplied in New Zealand by:

Orion Pharma (NZ) Limited

c/o Max Health Ltd

PO Box 44452

Pt Chevalier, Auckland 1246

Telephone: (09) 815 2664

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