NEW ZEALAND CONSUMER MEDICINE INFORMATION

PACIFIC BUSPIRONE  
Buspirone hydrochloride tablets 5 mg & 10 mg

What is in this leaflet
This leaflet answers some common questions about Pacific 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 taking Pacific Buspirone against the benefits they expect it will have for you.

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

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

What Pacific Buspirone is used for
Pacific Buspirone is used to treat anxiety over short periods of time. The way it works is unknown. It does not relax muscles or cause drowsiness in most patients.

Pacific Buspirone contains the active ingredient buspirone hydrochloride. It belongs to a group of medicines called anxiolytics.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

There is no evidence that Pacific Buspirone is addictive.

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

Before you take Pacific Buspirone

When you must not take it:
Do not take Pacific Buspirone if you have an allergy to:

- any medicine containing buspirone hydrochloride
- any of the 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 give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Do not take Pacific Buspirone if you have or have had severe liver disease.

Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:
Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have or have had any medical conditions, especially the following:

- any problems with your kidneys or liver
- if you have ever had convulsions, fits or seizures.

Tell your doctor if you are taking a monoamine oxidase inhibitor like phenelzine or tranylcypromine. Your doctor may change your medicines.

If you have not told your doctor about any of the above, tell him/her before you start taking Pacific Buspirone.

Taking other medicines
Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Pacific Buspirone may interfere with each other. These include:

- monoamine oxidase inhibitors like phenelzine or tranylcypromine
- selective serotonin re-uptake inhibitors like fluoxetine, fluvoxamine, paroxetine and sertraline
- any other anti-depressant medicine, sleeping tablets or medicine given to calm the nerves or to improve moods
- medicines known as benzodiazepines, such as diazepam, alprazolam or temazepam
- medicines used to treat certain mental and emotional conditions, such as haloperidol and nefazodone

Tell your doctor if you are taking:

- any medicine containing buspirone hydrochloride
- any of the 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 give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine/it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.
• antibiotics like erythromycin or rifampicin
• medicines used to treat fungal infections, such as itraconazole or ketoconazole
• medicines used to treat viral infections, such as ritonavir
• medicines used to treat high blood pressure or angina, such as diltiazem or verapamil
• anticonvulsants, such as phenytoin, phenobarbitone, or carbamazepine
• dexamethasone, a medicine used to treat inflammation.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Pacific Buspirone

Follow all directions given to you by your doctor or pharmacist carefully.
They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much Pacific Buspirone you need to take each day. This depends on your condition and whether or not you are taking other medicines.

The starting dose is usually one 5 mg tablet taken three times a day. It may be necessary to increase the dose by 5 mg a day every 2 to 3 days to get a good response.

This is usually reached at around two to three 10 mg tablets a day, taken in two or three doses.

No more than six 10 mg tablets should be taken in 24 hours.

Elderly people should take no more than three 10 mg tablets in 24 hours.

How to take it

Swallow the tablets with a full glass of water.

When to take it

Take your medicine at about the same times each day.
Taking it at the same times each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food, but you should take it consistently with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.
This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember (as long as it is 6 hours before the next dose is due), 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.
This may increase the chance of you getting an unwanted side effect.

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 Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Pacific Buspirone. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Pacific Buspirone, you may feel sick and may vomit. You may also feel dizzy, drowsy, and your eyesight may be affected.

While you are using Pacific Buspirone

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do

Do not take Pacific Buspirone to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not drink alcohol while you are taking Pacific Buspirone.

Do not eat grapefruit or drink grapefruit juice while you are taking Pacific Buspirone.

Things to be careful of

Be careful driving or operating machinery until you know how
Pacific Buspirone affects you. This medicine may cause dizziness, headache, drowsiness, light-headedness and nausea in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pacific Buspirone. This medicine helps most people with anxiety but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness
- headache
- drowsiness
- nausea or vomiting
- constipation
- diarrhoea
- insomnia
- nervousness
- feeling lightheaded
- unusual tiredness
- disturbed dreams
- blurred vision
- dry mouth or sore throat
- nasal congestion
- rash.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the throat or tongue
- chest pain
- confusion
- fast pounding heartbeat
- fever
- mental depression
- incoordination
- muscle weakness; numbness, tingling, pain or weakness in hands or feet
- stiffness of arms or legs;
- uncontrolled movements of the body
- fainting
- hallucinations
- urinary retention
- Serotonin Syndrome: restlessness, confusion, agitation, feeling overheated or excessive sweating, euphoria, racing heartbeat, confusion and concentration problems, shakiness, difficulty with reflexes, excessive salivation, rapid contraction and relaxation of the ankle muscle causing abnormal movements of the foot, abnormal movements of the jaw, clumsiness, feeling intoxicated or dizzy, muscle twitching, rigidity.

The above list includes serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

After taking Pacific Buspirone

Storage

Keep your tablets in the bottle until it is time to take them.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Pacific Buspirone or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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 this medicine 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

Pacific Buspirone tablets are available in two strengths – 5 mg and 10 mg.

The 5 mg tablets are white, round tablets, marked “BR 5” on one side and “G” on the other side.

The 10 mg tablets are white, capsule shaped tablets, marked “BR” breakline “10” on one side and “G” on the other side.

Ingredients

Pacific Buspirone contains 5 mg or 10 mg of buspirone hydrochloride as the active ingredient.

It also contains:

- lactose
- microcrystalline cellulose
- sodium starch glycollate
- colloidal silicon dioxide
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine
Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

**Date of Information**

9 April 2014
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