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Provision For Pharmacode.
Size: 20 x 10 mm
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Package leaflet: Information for the patient

Buspirone hydrochloride 5 mg, 10 mg, 15 and 30 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

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

Buspirone 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 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 tablets

Do not take Buspirone tablets and tell your doctor if you:
- are **allergic** (hypersensitive) 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 you take Buspirone 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 You should be gradually withdrawn from these medicines before taking Buspirone tablets.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 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 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, phenytoin, carbamazepine (to treat epilepsy)
- cimetidine (to treat stomach ulcers)
- diazepam (to treat anxiety)
- warfarin (to treat blood clots)

Buspirone tablets with food or drink

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

Always take Buspirone tablets 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 tablets should be taken consistently with or without food.

Doses:
Adults (including the elderly)
The usual 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. The maximum daily dosage should not exceed 60 mg per day.

Use in Children and Adolescents

Buspirone tablets are not recommended for use in children or adolescents under the age of 18.

Patients with liver or kidney problems – If you have liver or kidney problems, your doctor may prescribe you a lower dose.

If you take more Buspirone tablets 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,

Back Side
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Provision For Pharmacode
Size: 20 x 10 mm
320.0 mm
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15 mm

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 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 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.

The tablet can be divided into equal halves.

4. Possible side effects

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

Stop taking Buspirone 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).

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
- Psychosis, hallucinations, feeling that the mind is separated from the body, effect on your lability, fits, tunnel vision, 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), fainting or passing out, 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 or 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 tablets
Keep this medicine out of the sight and reach of children.

Do not use after the expiry date stated on the carton (EXP). The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 tablets contain

- The active substance is buspirone hydrochloride.
- Each tablet contains 5mg, 10mg, 15mg or 30mg of the active substance.
- The other ingredients are lactose, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, silica colloidal anhydrous

What Buspirone tablets looks like and contents of the pack

5 mg tablets are white to off white, flat faced, capsule shaped tablet, scored on one side and debossed with "098" on other side.

10 mg tablets are white to off-white, flat faced, capsule shaped tablet, scored on one side and debossed with "099" on other side.

15 mg tablets are white to off-white, flat faced, capsule shaped tablet, scored and debossed with 5/5/5 on one side and 1/00 on other side.

30 mg tablets are white to off-white, flat faced, capsule shaped tablet, scored and debossed with 10/10/10 on one side and 1/01 on other side.

Buspirone tablets are supplied in

5mg: Blister pack containing 21, 30, 56, 60, 84 & 90 tablets.

10mg: Blister pack containing 21, 30, 56, 60, 84 & 90 tablets.

15mg: Blister pack containing 21, 30, 56, 60, 84 & 90 tablets.

30mg: Blister pack containing 21, 30, 56, 60, 84 & 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Wave Pharma Limited,
Ground floor Cavendish House,
369 Burnt Oak Broadway,
Edgware, HA8 5AW,
United Kingdom

If you would like this leaflet in a different format or register a complaint, please contact the Marketing Authorisation holder listed above.

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