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Package leaflet: Information for the patient

Buspirone hydrochloride 7.5 mg Tablets

Buspirone hydrochloride

The name of your medicine is 'Buspirone hydrochloride 7.5 mg Tablets' but it will be referred to as 'Buspirone' throughout this leaflet.

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, pharmacist or nurse.
- 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 is and what it is used for

Buspirone contains the active ingredient buspirone hydrochloride, which belongs to a group of medicines called anxiolytics. These medicines work on the central nervous system, altering levels of chemicals in the brain.

Buspirone 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

Do not take Buspirone and tell your doctor:
- if you are **allergic** to buspirone hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are **pregnant** or **breast-feeding.**
- if you have **epilepsy.**
- if you have **severe problems** with the way your liver or kidney work (**severely** impaired **liver** or **kidney** function).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Buspirone:
- if you have had problems with the way your liver or kidneys work (impaired **liver** or **kidney** function) in the past;
- if you have been prescribed a **benzodiazepine** for example nitrazepam or temazepam or another common **sedative** or **hypnotic** medicine. You should be gradually withdrawn from these medicines before taking Buspirone.
- if you have an eye disease called **acute narrow-angle glaucoma;**
- if you have **myasthenia gravis**, a disorder characterised by muscle weakness, difficulty chewing or swallowing and slurred speech;
- or if you have had **drug dependence**

Other medicines and Buspirone

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) for example 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 medicines for example 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 for example 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 with food, drink and alcohol

Talk to your doctor before eating or drinking products containing grapefruit juice, while taking Buspirone.

You should not drink alcohol while taking Buspirone.

Pregnancy, breast-feeding and fertility

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.

Driving and using machiness

Buspirone 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 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.

Buspirone tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'

3. How to take Buspirone

Always take this medicine 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 should be taken consistently with or without food. The way the medicine is taken on the first day of treatment should be continued thereafter.

Doses

Adults (including the older people)

The usual starting dose is 5 mg two to three times a day, which may be increased every two to three days. The usual dose you will be maintained on is 15 mg to 30 mg a day in divided doses up to a maximum dose of 45 mg a day in divided doses.

Use in children

This medicine is not recommended for use in children.

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Dimension - 150 x 310 mm

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Font size: 9 points
No. of Columns: 2 Columns

Front Side

ARTWORK DETAIL LABEL

Product	**Buspirone Hydrochloride - 7.5 mg**				
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	**150 x 310 mm**			Pack	---
New Item Code	**1047061**	Old Item Code	1037748		
Colour Shades	**Black**			No. of Colours	1

Change Control No.	PC-TSG/2022/046 Record Number: 333148	Artwork Version	2.0
Design/Style	Front & Back side printing, to be supplied in the Unfolded size.		
Substrate	60 GSM paper.		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	**Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.**		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

Use in patients with liver and kidney problems
If you have problems with the way your liver or kidney work (impaired liver or kidney function), your doctor may prescribe you a lower dose.

If you take more Buspirone 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 (nausea or vomiting), headache, dizziness, drowsiness, ringing or buzzing in the ears, restlessness, restriction of the pupils, stomach problems, slow heart beat, low blood pressure, fits and 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 (extrapyramidal symptoms).

If you forget to take Buspirone
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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Buspirone
Talk to your doctor before you stop taking the tablets and follow their advice.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Buspirone and contact your doctor immediately if you experience: **high fever, agitation, confusion, trembling and abrupt contractions of muscles; these may be signs of a rare condition called serotonin syndrome.**

Contact your doctor immediately if you notice signs of an allergic reaction: itchy, skin rash, swelling of the face, lips, tongue or throat, or difficulty breathing or swallowing.

Very common side effects (may affect more than 1 in 10 people):
- dizziness
- headache
- drowsiness
- feeling nervous or excited.

Common side effects (may affect up to 1 in 10 people):
- nervousness
- inability to sleep
- disturbance in attention
- depression
- blurred vision
- confusion
- sleep disturbances
- anger
- tingling or pins and needles
- abnormal coordination, tremor
- buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus)
- chest pain
- fast heart beat
- blocked nose
- throat pain or soreness
- feeling sick (nausea)
- being sick (vomiting)
- dry mouth
- diarrhoea
- constipation
- abdominal pain
- cold sweat
- rash
- muscle and bone pain
- tiredness.

Rare side effects (may affect up to 1 in 1,000 people):
- symptoms such as wheezing, swelling of the face or tongue (angioedema)
- bruising
- hives.

Very rare side effects (may affect up to 1 in 10,000 people):
- severe mental conditions in which the person loses contact with reality and is unable to think and judge clearly (psychosis)
- seeing, feeling or hearing things that are not there (hallucination)
- change in personality
- mood swings
- fits or seizures
- unusual, uncontrollable movements such as twitching or spasms which may affect the hands, the eyes and the rest of the body resulting in for example increased hand tremor, muscle twitching, muscle cramp, irregular movement of jaw muscles resulting in difficulty opening the mouth (ataxia)
- fainting
- loss of memory
- restlessness or difficulty standing still
- restricted vision
- feeling of uneasiness and restlessness in the legs, especially after going to bed (restless legs syndrome)
- difficulty passing urine
- secretion of breast milk in men, or in women who are not breast-feeding.

Reporting of side effects
If you get 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 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
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special storage conditions.
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 Buspirone contains
- The active substance is buspirone hydrochloride. Each tablet contains 7.5 mg buspirone (as hydrochloride).
- The other ingredients are: lactose monohydrate, microcrystalline cellulose (Avicel- PH-101), sodium starch glycolate Type A, micro-crystalline cellulose (Avicel-PH-200), colloidal silicon dioxide and magnesium stearate.

What Buspirone looks like and contents of the pack
The tablets are white to off white colour, oval, biconvex tablets debossed with '7.5' on one side and plain on other side. The dimensions of the tablets are 10.0 mm x 6.0 mm.

Blister pack sizes of 20, 30, 40, 50, 60, 90 and 100 tablets are available.

HDPE bottles of 30, 60 and 100 tablets are available.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer
Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane, Watford, Hertfordshire WD18 9SS, United Kingdom.

This leaflet was last revised in 04/2022

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