

11241

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Baclofen Tablets BP 10mg

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 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Baclofen tablets are and what they are used for
- What you need to know before you take Baclofen tablets
- How to take Baclofen tablets
- Possible side effects
- How to store Baclofen tablets
- Contents of the pack and other information.

Please read this product information carefully before you or your child is given Baclofen since it contains important information.

1. WHAT BACLOFEN TABLETS ARE AND WHAT THEY ARE USED FOR

Baclofen belongs to a group of medicines called anti-spasticity agents, which are used to relax muscles.

Your doctor has decided that you or your child needs this medicine to help treat your condition.

Baclofen is used to reduce and relieve the excessive tension in your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, cerebrovascular accidents, spinal cord diseases and other nervous system disorders.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BACLOFEN TABLETS

Do not take Baclofen tablets if you:

- are allergic to baclofen or any of the other ingredients of this medicine (listed in section 6).
- have a stomach ulcer

Warnings and precautions:

Talk to your doctor, or pharmacist or nurse before taking this medicine if you have any of the following:

- have a history of alcoholism, or you drink alcohol to excess or you have a history of drug abuse or dependence

Some people being treated with baclofen have had thoughts of harming or killing themselves or have tried to kill themselves. Most of these people also had depression, had been using alcohol excessively or were prone to having thoughts of killing themselves. If you have thoughts of harming or killing yourself at any time, speak to your doctor straightaway or go to a hospital. Also, ask a relative or close friend to tell you if they are worried about any changes in your behaviour and ask them to read this leaflet.

- depression or a mental disorder, especially if you are taking lithium
- liver or kidney disease
- breathing difficulties or lung disease
- high blood pressure and are being treated with antihypertensive medicines
- suffered from stomach ulcers in the past
- Parkinson's Disease
- There have been reports of reduction in brain function (encephalopathy) in some patients taking baclofen tablets at prescribed doses, which resolved after stopping the medication. Symptoms include increased sleepiness, new onset of drowsiness,

- confusion, muscle jerks or coma. If you experience any of these symptoms, seek medical attention immediately. Your physician will decide whether baclofen has to be discontinued.
- diabetes, as your doctor may want to monitor your condition
- recently suffered from a stroke
- epilepsy
- difficulty urinating (urinary retention)
- pregnant, intend to become pregnant or are breast feeding.

Children and adolescents:

Baclofen tablets are not suitable for use in children under 33 kg body weight.

Other medicines and Baclofen tablets:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because Baclofen Tablets can affect the way some medicines work. Please check with your doctor if you are taking any of the following:

- other medicines to relax muscles e.g tizanidine
- antidepressants such as clomipramine, amitriptyline or lithium
- medicine to help lower blood pressure, as your doctor may want to monitor your blood pressure e.g. diltiazem
- Other drugs which also affect the kidney, e.g. ibuprofen (usually for arthritis or pain relief)
- levodopa and carbidopa for Parkinson's Disease (as taking these together may cause mental confusion, hallucinations, agitation)
- medicines which slow down the nervous system, e.g. promethazine, temazepam, opiates for pain relief such as morphine and anti-convulsants (anti-epileptic medicines such as carbamazepine).
- If you are due to have an operation requiring a general anaesthetic, make sure you tell the doctor that you are taking baclofen.

Taking Baclofen tablets with food and drink:

Do not drink alcohol whilst taking Baclofen Tablets.

You should take the tablets with food or a drink of milk, especially if you feel sick when you take them.

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.

Baclofen should only be used during pregnancy, if considered strictly necessary, especially during the first three months.

If you have to take Baclofen tablets during pregnancy, your unborn baby will also be exposed to this medicine and after birth the baby may develop withdrawal symptoms such as convulsions.

Only a very small amount of baclofen passes into breast milk. Your doctor will decide if this medicine is to be prescribed whilst breast-feeding.

Driving and using machines:

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are taking Baclofen Tablets. If this happens, you should not drive or do anything that requires you to be alert (such as operate tools or machinery) until the effects have worn off.

Baclofen 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 medicine.

Sodium

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

3. HOW TO TAKE BACLOFEN TABLETS

Always take Baclofen tablets exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

You should take the tablets with food or a drink of milk, especially if you feel sick when you take them.

Adults

The usual initial dose is 5 mg baclofen three times a day for three days. Then 10mg baclofen three times a day for the next three days. Then 15mg baclofen three times a day for three days, followed by 20mg baclofen three times a day for the next three days.

200 x 260 mm

FRONT SIDE

ARTWORK DETAIL LABEL				MFG. LOCATION: KRSG	
Product	Baclofen Tablets BP - 10mg				
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	200 x 260mm			Pack	-----
New Item Code	1051086	Old Item Code	1048402		
Colour Shades	<div><div></div> BLACK</div>			No. of Colours	1
Change Control No.	PC-ODF/2024/504 - Record Number: 429685			Artwork Version	14.0
Design/Style	Front & Back Printing. To be supplied in UNFOLDED size.				
Substrate	60 GSM Paper.				
Special Instructions	Printing clarity to be clear & 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.					

The usual daily dose thereafter is 60mg baclofen (two tablets three times a day). Your doctor may increase the dose prescribed up to 100mg baclofen per day or sometimes more if you are in hospital.

The daily dose may be taken divided up in to three doses, or it may be taken just at night time to help painful night cramp, or it may be taken approximately 1 hour before doing specific tasks such as washing, dressing or physiotherapy, which are helped by taking baclofen. Your doctor will tell you what is best for you.

Elderly

Elderly patients will usually start with a smaller daily dose of baclofen.

Use in children (0 to <18 years):

Children's treatment is adjusted to their body weight. Children's treatment usually starts with a very low dose (approximately 0.3mg/kg/day), in 2-4 divided doses (preferably in 4 doses).

The dosage is then gradually increased until it becomes sufficient for the child's individual requirements, this may be between 0.75 and 2mg/kg body weight. The total daily dose should not exceed a maximum of 40mg/day in children below 8 years of age. In children over 8 years of age a maximum daily dose of 60mg/day may be given. Baclofen tablets are not suitable for use in children below 33 kg body weight.

If you take more Baclofen tablets than you should:

An overdose of this medicine may be harmful.

Sign of overdose is:

- ringing in the ears

If you or someone else, have taken too much of your medicine tell your doctor or pharmacist, or go to the nearest hospital casualty department immediately. Take your medicine with you.

If you forget to take Baclofen tablets:

If you forget to take a dose at the right time, take it as soon as you remember, then go one as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Baclofen tablets:

Do not stop taking baclofen suddenly unless your doctor tells you to. If you stop taking your Baclofen Tablets without gradually reducing the dose you may suffer from unpleasant side effects such as worsening of spasticity and muscle rigidity, rhabdomyolysis (a serious syndrome due to muscle injury), fast heart rate, fever, anxiety, delusions, hallucinations, changed behaviour, hyperactivity, abnormally high body temperatures, confusion, abnormal muscle movements, convulsions or palpitations.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Baclofen Tablets can cause side effects, although not everybody gets them.

The side effects listed below have been reported:

More than 1 in 10 people have experienced:

Tiredness, sleepiness, nausea (feeling sick).

Up to 1 in 10 people have experienced:

- Excessively weak limbs or feeling tired and exhausted, aching muscles
- Headache, dizziness or light-headedness
- Breathing difficulties
- Sleeplessness
- Mood changes, confusion, hallucinations or nightmares
- Dry mouth
- Problems with their eyes
- Unsteadiness, trembling or other problems with muscle control
- Low blood pressure (fainting)
- Stomach problems including retching, vomiting, constipation and diarrhoea
- Excessive sweating, rash
- Increased need to pass urine or pain on passing urine.

Up to 1 in 1,000 people have experienced:

- Numbness or tingling in hands or feet
- Increased muscle spasm
- Disturbed sense of taste

- Slurred or slow speech
- Stomach ache
- Liver problems
- Difficulty in passing urine
- Sexual problems in men, e.g. impotence
- Convulsions (particularly in epileptics).

Very rarely (less than 1 in 10,000) people have experienced:

- Hypothermia (low body temperature).

Other side-effects (how often they happen is not known)

- Raised, itchy rash (urticaria – also known as nettle rash or hives).
- Slow heart beat.
- Increase in blood sugar.
- Trouble breathing during sleep (sleep apnoea syndrome).
- Reduction in brain function (encephalopathy)

Symptoms caused by stopping treatment suddenly (see '3. How to take Baclofen Tablets').

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to adjust the dose or give you a different medicine.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or AppleApp Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BACLOFEN TABLETS

Keep out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the container tightly closed. Store in the original package.

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 Baclofen tablets contain:

Each tablet contains 10mg of the active ingredient Baclofen.

Each tablet also contains microcrystalline cellulose, lactose, calcium hydrogen phosphate, colloidal anhydrous silica, magnesium stearate and sodium starch glycollate.

What Baclofen tablets look like and the contents of the pack

Baclofen Tablets are white round, flat bevelled edge tablet marked "BN" breakline "10" on one side and plain on the reverse.

The tablets are supplied in Polypropylene containers with polyethylene caps (with optional use of fillers)

Pack sizes: 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250, 500

Blister packs of Alu/PVC/PVDC.

Pack sizes: 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180

Not all pack sizes may be marketed.

Marketed Authorisation Holder and Manufacturer
Strides Pharma UK Ltd.
Unit 4, The Metro Centre, Dwight Road,
Watford, WD18 9SS, UK

This leaflet was last revised in 08/2024.

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1051086

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200 x 260 mm

BACK SIDE

ARTWORK DETAIL LABEL

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Change Control No.	PC-ODF/2024/504 - Record Number: 429685			Artwork Version	14.0
Design/Style	Front & Back Printing. To be supplied in UNFOLDED size.				
Substrate	60 GSM Paper.				
Special Instructions	Printing clarity to be clear & sharp.				
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.				
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