

**Package leaflet: Information for the user**  
**Baclofen 5 mg/5 mL Oral Solution**

Baclofen

**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 Baclofen Oral Solution is and what it is used for
2. What you need to know before you take Baclofen Oral Solution
3. How to take Baclofen Oral Solution
4. Possible side effects
5. How to store Baclofen Oral Solution
6. Contents of the pack and other information

**1. What Baclofen Oral Solution is and what it is used for**

Baclofen Oral Solution contains the active substance baclofen.  
 Baclofen is a muscle-relaxant.  
 Baclofen is a muscle-relaxant drug. Baclofen oral solution 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 Oral Solution**

**Do not take this medicine:**

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

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Baclofen Oral Solution:

- if you have a history of alcoholism, or your 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.

- if you suffer from epilepsy
- if you have difficulties in urinating
- if you suffer from any liver, kidney or lung disease
- if you suffer from mental illness, for example: depression, manic disorders, schizophrenia, psychotic disorders or confused states
- if you suffer from diabetes
- if you are being treated for high blood pressure
- if you suffer from Parkinson's disease
- if you are pregnant, trying to become pregnant or are breast-feeding
- if you have had a stroke, a "mini stroke" (transient ischaemic attack) or have been told you may be at risk of these.

There have been reports of reduction in brain function (encephalopathy) in some patients taking baclofen oral solution 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.

If the answer to any of these questions is YES, tell your doctor or pharmacist because Baclofen oral solution might not be the right medicine for you.

Tell your doctor before taking this medicine if you have been told that you have an **intolerance to some sugars**.

This is because Baclofen Oral Solution contains sorbitol, a type of sugar.

**Other medicines and Baclofen Oral Solution**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without prescription. In particular tell your doctor if you are taking any of the following:

- Other medicines to relax muscles e.g. tizanidine
- medicines to treat mood disorder such as lithium, or tricyclic antidepressants such as amitriptyline
- medicines that lower blood pressure including medicines used to treat high blood pressure e.g. diltiazem
- medicines for arthritis or pain, e.g. ibuprofen (which also affects kidney)
- medicines which slow down the nervous system, e.g. anti-histamines such as promethazine, sedatives such as temazepam, opiates for pain relief such as morphine and anti-convulsants (anti-epileptic medicines such as carbamazepine).
- sedatives or sleeping tablets e.g. diazepam
- medicines for Parkinson's disease e.g. levodopa or carbidopa

Always tell your doctor or pharmacist about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor*

**Baclofen Oral Solution with alcohol**

Be careful when drinking **alcohol** - it may affect you more than usual.

**Other special Warnings**

- Whilst you are taking this medicine, your doctor may want to give you a **check up** from time to time.
- Tell your doctor that you are taking Baclofen Oral Solution if you are going to have an **operation** of any kind.

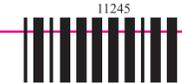
**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine. You should not take this medicine during pregnancy unless your doctor advises you to do so. Tell your doctor if you are pregnant or planning to become pregnant. If you have to take baclofen 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 discuss with you whether you should breast-feed whilst taking Baclofen Oral Solution.

**Driving and using machines**

This medicine can make you feel drowsy, dizzy or cause blurred vision. Do not drive or operate machinery if you are affected.



**Baclofen Oral Solution contains methyl para hydroxybenzoate(E218) and propyl para hydroxybenzoate(E216) and sorbitol**

- Small amounts of the preservatives methyl para hydroxybenzoate and propyl para hydroxybenzoate. These can sometimes cause allergic reactions possibly delayed which might appear sometime after first taking the medicine.
- This medicine contains 3275 mg sorbitol in each 5ml of syrup. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

**Information on Sodium content**

This medicine contains less than 1 mmol sodium (23mg) per 5ml, that is to say essentially 'sodium free'. When the dose is greater than 14ml it cannot be considered 'sodium free' and it should be taken into consideration by patients on a controlled sodium diet. At maximum daily dose (120ml) this medicine contains 194.4mg of sodium. This is equivalent to 9.72% of the recommended maximum daily dietary intake of sodium for an adult.

**3. How to take Baclofen Oral Solution**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The doctor will tell you the best time to take the medicine. Some people take it only at night or before doing a task such as washing, dressing, shaving, etc.

The final dose of baclofen oral solution depends on how each person responds to the drug. You will be started on a low dose, and this will be increased gradually over a few days, under the supervision of the doctor, until you are having the dose which is right for you. If the starting dose is too high, or if the dose is increased too quickly, you may experience side effects, particularly if you are elderly, have kidney problems or have had a stroke.

If you feel sick after taking baclofen oral solution, you may find it helps to take it with food or a milk drink.

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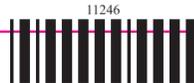
Front Side

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**ARTWORK DETAIL LABEL**

<b>Product</b>	<b>Baclofen 5mg/5ml - Oral Solution</b> (BELTAPHARM)			
Buyer/Country	SPUK	Component	Pack Insert	
<b>Dimension</b>	<b>430 x 160 mm</b>	Pack	--	
<b>New Item Code</b>	<b>1051104</b>	Old Item Code	1050774	
Colour Shades	■ BLACK	No. of Colours	1	
Change Control No.	PC-TSG/2024/057 - Record Number: 429714		Artwork Version	7.0
Design/Style	Front & Back Printing. To be supplied in folded size 53.75 x 160 mm-Brand name facing front side after final fold.			
Substrate	40 GSM Bible Paper.			
Special Instructions	Printing clarity to be clear & sharp.			
Autocartanator Requirements	NA			
Prepared By:	Reviewed By:	Approved By:	Approved By:	Authorised By:
PDC - AW	PDC - Tech	Mkt/BD	RAD	QA
<b>FOR ARTWORK REVISION PURPOSE</b>				
To be filled by SCM (Planning)	Effective Date:	Sign & Date:		
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**Adults**

- The usual dose is 20 mg (20 mL) three times a day.
- The maximum daily dose is 100 mg (100 mL) expect if you are in hospital when a higher dose may be used.

**Elderly patients**

The dose may be reduced for elderly patients.

**Use in children and adolescents (under 18 years of age)**

Children's treatment is adjusted to their body weight and usually starts with a very low dose (approximately 0.3 mg/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 2 mg/kg body weight.

The total daily dose should not exceed a maximum of 40 mg/day in children below 8 years of age. In children over 8 years of age a maximum daily dose of 60 mg/day may be given.

**If you have kidney problems**

You will probably be given a much lower dose. The doctor will decide what the dose should be.

**If you take more Baclofen Oral Solution than you should**

If you accidentally take too much baclofen oral solution, tell your doctor at once or contact your nearest hospital casualty department. Take your medicine with you. Signs of overdose are: Ringing in the ears.

**If you forget to take Baclofen Oral Solution**

If you forget to take a dose, take the next dose at the usual time. DO NOT take a double dose to make up for a forgotten dose.

**If you stop taking Baclofen 5 mg/5 mL Oral Solution**

You should not stop taking baclofen oral solution suddenly. If the doctor decides to stop your treatment with baclofen oral solution, the dose will be reduced gradually to prevent withdrawal such as muscle spasms and increased muscle rigidity, too much muscle tone, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feeling persecuted or convulsions (fits).

**4. Possible side effects**

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

**The side effects listed below have been reported:****Very common side effects** (may affect more than 1 in 10 people):

Tiredness, sleepiness, nausea (feeling sick).

**Common side effects** (may affect up to 1 in 10 people):

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

Blurred or double vision, difficulty in focussing, trembling or flicking of the 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.

**Rare side effects** (may affect up to 1 in 1,000 people):

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 rare side effects** (may affect up to 1 in 10,000 people):

Hypothermia (low body temperature)

**Not known side effects** (frequency cannot be estimated from the available data):

Raised itchy rash (urticaria – also known as nettle rash or hives).

Slow heart rate (Bradycardia)

Increase in blood sugar.

Trouble breathing during sleep (sleep apnoea syndrome)

Reduction in brain function (encephalopathy)

Swelling of the ankles, feet or lower legs

Swelling face

Allergic reaction (hypersensitivity)

Hair loss

Sexual difficulties

Symptoms caused by stopping treatment suddenly (see section 3)

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](http://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 Baclofen 5 mg/5 mL Oral Solution**

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after 'EXP'. The expiry date refers to the last day of that month.

Do not use after the expiry date that is stated on the carton and bottle label. Once opened the solution should be used within 60 days. Protect from light. Do not refrigerate.

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 5 mg/5 mL Oral Solution contains**

The active substance is baclofen. Each 5 ml of solution contains 5 mg baclofen.

The other ingredients are: liquid sorbitol (non-crystallising) (E420), methyl paraben (E218), propyl paraben (E216), flavour raspberry, carmellose sodium (E466) and purified water.

**What Baclofen 5 mg/5 mL Oral Solution looks like and contents of the pack**

Baclofen 5 mg/5 mL Oral Solution is a clear, slightly yellow solution with a raspberry flavour. It is packaged in 300ml amber glass bottles with child proof closures.

**Marketing Authorisation Holder and Manufacturer****Marketing Authorisation Holder**

Strides Pharma UK Ltd.

Unit 4, The Metro Centre

Dwight Road, Watford, WD18 9SS, United Kingdom

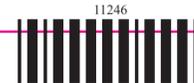
**Manufacturer**

Beltapharm S.P.A

Via Stelvio, 66,

20095 Cusano Milanino (MI), Italy

This leaflet was last revised in 08/2024



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Special Instructions	Printing clarity to be clear & sharp.				
Autocartonnator Requirements	NA				
Prepared By:	Reviewed By:	Approved By:	Approved By:	Authorised By:	
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<b>FOR ARTWORK REVISION PURPOSE</b>					
To be filled by SCM (Planning)	Effective Date:		Sign & Date:		
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