

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

**1. What Baclofen 5 mg/5 mL Oral Solution is and what it is used for**

Baclofen 5 mg/5 mL Oral Solution contains the active substance baclofen. Baclofen is a muscle-relaxant. 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, head injuries, spinal cord diseases and other nervous system disorders.

**2. What you need to know before you take Baclofen 5 mg/5 mL 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 5 mg/5 mL

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
- if you have a history of depression, had been using alcohol excessively or were prone to having thoughts of killing 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 passing water
- 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.

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

This is because Baclofen 5 mg/5 mL Oral Solution contains sorbitol, a type of sugar.

**Other medicines and Baclofen 5 mg/5 mL 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:

- medicines for mood disorder, e.g. tricyclic antidepressants, lithium
- medicines for high blood pressure
- medicines for arthritis or pain, e.g. ibuprofen (which also affects kidney)
- medicines which slow down the nervous system, e.g. antihistamines
- sedatives or sleeping tablets e.g. diazepam
- medicines for pain relief e.g. morphine or codeine
- medicines for epilepsy e.g. phenytoin or carbamazepine
- medicines for Parkinson's disease e.g. levodopa or carbidopa

**Baclofen 5 mg/5 mL 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 5 mg/5 mL Oral Solution if you are going to have an **operation** of any kind.

**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.

You should not take this medicine during pregnancy unless your doctor advises you to do so.

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 5 mg/5 mL 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 5 mg/5 mL Oral Solution contains methyl para hydroxybenzoate and propyl para hydroxybenzoate, sodium and sorbitol**

This medicinal product contains:

- 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.
- 0.65 to 1.08 mg/mL sodium per 1 mL of syrup. Take this into consideration if you are on a controlled sodium diet.
- Sorbitol. This can have a mild laxative effect and you might be affected if you take more than 25 ml of Baclofen 5mg/5mL Oral Solution per day. Calorific value 2.6 kcal/g sorbitol. 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.

**3. How to take Baclofen 5 mg/5 mL 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.

In all patients the dose is increased gradually, usually every 3 days, starting with a dose of 5 mg (5 mL) per day. Each dose should be taken during meals with a little liquid. The final dose depends on how you respond.

The usual doses of Baclofen 5 mg/5 mL Oral Solution are as follows:

**Adults**

- 20 mg (20 mL) three times a day.
- The maximum daily dose is 100 mg (100 mL).

Dimension: 430 x 160 mm

Font : Times New Roman 9 pt.

Front Side

**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>1043512</b>	Old Item Code	1039997	
Colour Shades	■ BLACK	No. of Colours	1	
Change Control No.	Record Number: 321874			Artwork Version 5.0
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 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:		
<b>Caution to the printer:</b> 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. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>				

RD/PD/003/F-01/R0



However some patients take it only at night or about one hour before doing a task such as washing, dressing, shaving or having physiotherapy.

If you are in hospital, 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**

A lower dose of 5 mg (5 mL) daily may be used.

If you are not sure about how much medicine to take, please speak to your doctor or pharmacist.

Shake the bottle well before you take your medicine.

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

**If you take more Baclofen 5 mg/5 mL Oral Solution than you should**

Signs of overdose are:

- Ringing in the ears

If you accidentally take too much of your medicine, tell your doctor **at once** or contact your nearest hospital casualty department. Take your medicine with you.

**If you forget to take Baclofen 5 mg/5 mL Oral Solution**

If you forget to take a dose, just 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**

**Do not stop** taking your medicine suddenly; unwanted effects such as muscle spasms and increased muscle rigidity, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feeling persecuted or convulsions (fits) may occur. Ask your doctor how to reduce the dose gradually.

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.

**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)
- Drug withdrawal syndrome
- Blood glucose increased
- Trouble breathing during sleep (sleep apnoea syndrome)
- Symptoms caused by stopping treatment suddenly (see section 3)

**Reporting of side effects**

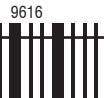
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow 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, Metro Centre, Tolpits Lane, Watford, Hertfordshire  
WD18 9SS, United Kingdom

**Manufacturer**

Beltapharm S.P.A  
Via Stelvio, 66,  
20095 Cusano Milanino (MI), Italy

**This leaflet was last revised in 10/2021**



1043512

Dimension: 430 x 160 mm Font : Times New Roman 9 pt.

Back Side

**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>1043512</b>	Old Item Code	1039997	
Colour Shades	■ BLACK	No. of Colours	1	
Change Control No.	Record Number: 321874		Artwork Version	5.0
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 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:		
<b>Caution to the printer:</b> 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. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>				