140mm

330mm

Package leaflet: Information for the patient

Baclofen 25mg Tablets

What you need to know about Baclofen Tablets
Your doctor has decided that you or your child needs this medicine to help treat your condition.

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

What is in this leaflet

1. What Baclofen Tablets are and what they are used for
2. What you need to know before you take Baclofen Tablets
3. How to take Baclofen Tablets
4. Possible side effects
5. How to store Baclofen Tablets
6. Contents of the pack and other information

1. What Baclofen Tablets are and what they are used for

Baclofen 25mg tablets contain 25mg of the active ingredient, baclofen. Baclofen is a muscle-relaxant drug. Baclofen Tablets are 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

Some people MUST NOT take Baclofen Tablets. Talk to your doctor if you:
- are allergic to baclofen or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include rash, itching and swelling of the face, lips, throat or tongue
- have ever had a stomach ulcer.

Warnings and precautions
Talk to your doctor or pharmacist before taking Baclofen if you:
- have suffered from a stroke
- suffer from epilepsy
- suffer from any mental illness
- are being treated for high blood pressure
- have Parkinson's disease
- suffer from any liver, kidney or lung disease
- have diabetes
- have difficulty urinating
- are pregnant or breast-feeding (See section "**Pregnancy, breast-feeding and fertility**").
- have a history of drug abuse or dependence

Other medicines and Baclofen Tablets
Some medicines can interfere with your treatment. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must tell your doctor if you are already taking any of the following medicines:
- Other medicines to relax muscles e.g. tizanidine
- Medicines to treat mood disorders such as lithium or tricyclic depressants such as amitriptyline
- Medicines that lower blood pressure including medicines used to treat high blood pressure e.g. diltiazem
- Medicines which affect the kidney e.g. ibuprofen
- Medicines for Parkinson's disease e.g. levodopa and carbidopa
- Medicines which slow down the nervous system, such as anti-histamines (e.g. promethazine), sedatives (e.g.temazepam), opiates for pain relief (e.g. morphine, fentanyl) and anti-epileptic medicines (e.g.carbamazepine).

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.*

Pregnancy, breast-feeding and fertility
Ask your doctor or pharmacist for advice before taking this medicine.
You should not use Baclofen 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 Baclofen. After birth, your baby may develop withdrawal symptoms such as convulsions (symptoms of withdrawal are described in the section "**If you stop taking Baclofen**".
Only a very small amount of Baclofen passes into breast milk. Your doctor will discuss with you whether you should breast-feed whilst taking this medicine.

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

Other special warnings
- Be careful when drinking alcohol - it may affect you more than usual
- 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.
- Your doctor may want to give you a check-up from time to time while you are taking Baclofen Tablets.
- If you are going to have an operation of any kind, make sure that the doctor knows that you are taking Baclofen Tablets.
- There have been reports of reduction in brain function (encephalopathy) in some patients taking baclofen 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

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

3. How to take Baclofen Tablets

The doctor will tell you how many Baclofen Tablets to take and when to take them. Always follow his/her instructions carefully. The dose will be on the pharmacist's label. Check the label carefully. If you are not sure, ask your doctor or pharmacist. 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 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 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 Tablets, you may find it helps to take them with food or a milk drink.

140mm

330mm

Adults:
- The usual dose is 20mg three times a day.
- The maximum daily dose is 100mg except if you are in hospital when a higher dose may be used.

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 0.3 mg/kg/day), in 2-4 divided doses (preferably in 4 doses). The dosage is then gradually increased until it becomes suffi-cient 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. Baclofen Tablets are not suitable for use in children be-low 33 kg body weight.

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

If you forget to take Baclofen Tablets
If you forget to take a dose, take the next dose at the usual time.
Do not take a double dose.

If you take more Baclofen Tablets than you should
If you accidentally take too many Baclofen tablets, 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 and decrease in brain function (encephalopathy).

If you stop taking Baclofen Tablets
You should not stop taking Baclofen tablets suddenly. If the doctor decides to stop your treatment with Baclofen tablets, the dose will be reduced gradually to prevent withdrawal symptoms 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

Baclofen tablets are suitable for most people, but like all medicines, they can sometimes cause side effects.
The side effects listed below have been reported:

Very Common: may affect more than 1 in 10 people:
- Tiredness, sleepiness, nausea (feeling sick).

Common: 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
- 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.

Rare: 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 rarely (less than 1 in 10,000 people:
- 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 heartbeat.
- Increase in blood sugar.
- Trouble breathing during sleep (sleep apnoea syndrome)
- Swelling of the ankles, feet or lower legs
- Swelling face
- Allergic reaction (hypersensitivity)
- Hair loss
- Sexual difficulties
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Tablets

Keep this medicine out of the sight and reach of children.
Do not store above 25ºC. Store in the original package in order to protect from moisture.
Do not use Baclofen Tablets after EXP.
The expiry date is stated on the carton and blister strip.
The expiry date refers to the last day of that month. If your tablets become discoloured or show any other sign of deterioration, please contact your doctor or pharmacist before taking your medicine.
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 to protect the environment.

6. Contents of the pack and other information

What Baclofen Tablets contains
The active substance (the ingredient that makes the tablets work) is Baclofen.

Each tablet contains 25 mg of Baclofen.

The other ingredients are microcrystalline cellulose (E460), maize starch, povidone, colloidal anhydrous silica (E551), and magnesium stearate (E572).

What Baclofen Tablets looks like and contents of the pack

White or almost white colored, round shaped flat tablets debossed with 'B' and '25' separated by break line on one side and plain on the other side.
Tablets are supplied in blister packs of 28, 56 and 84 Tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

NOUMED LIFE SCIENCES LIMITED
Noumed House, Shoppenhangers Road, Maidenhead, Berkshire, SL6 2RB, United Kingdom.

This leaflet was last revised in March 2026.

Other sources of information:
To listen to or request a copy of this leaflet in braille, large print or audio please call, 020 3399 8960 (UK only)
Please be ready to give the following information:

Product name:
Baclofen 25 mg Tablets
Reference number:
PL 44041/0127

L25BAC03/03

Pharmacode

Colour:

Black

NOTE: Pharmacode position is subject to change

Signature of Author:	
Signature of RA:	

Font Type & Size	**Main:** Times New Roman 12pts
	Body: Times New Roman 8.75pts

Title: Art Work Approval Form

Product	Baclofen 25 mg PIL			Specification:	
Customer	**NOUMED LIFE SCIENCES LIMITED, UK**				
Reason for Issue	Tablet Description update			Colours:	
				Dimensions:	140 x 330 (mm)
PL No.		Pharmacode No.		No. of Folds (only for PIL)	
Item Code	L25BAC03/03	Layout No.:			

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- Increased need to pass urine or pain on passing urine.

Rare: may affect up to 1 in 1,000 people:
- Numbness or tingling in hands or feet
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- 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: may affect up to 1 in 10,000 people:
- Hypothermia (low body temperature).

Not known: frequency cannot be estimated from available data
- Raised, itchy rash (urticaria – also known as nettle rash or hives).
- Slow heartbeat.
- Increase in blood sugar.
- Trouble breathing during sleep (sleep apnoea syndrome)
- Swelling of the ankles, feet or lower legs
- Swelling face
- Allergic reaction (hypersensitivity)
- Hair loss
- Sexual difficulties
- Reduction in brain function (encephalopathy)

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Pharmacode

Colour:

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NOTE: Pharmacode position is subject to change

Signature of Author:	
Signature of RA:	

Font Type & Size	**Main:** Times New Roman 12pts
	Body: Times New Roman 8.75pts

Title: Art Work Approval Form

Product	Baclofen 25 mg PIL			Specification:	
Customer	**NOUMED LIFE SCIENCES LIMITED, UK**				
Reason for Issue	Tablet Description update			Colours:	
				Dimensions:	190 x 265 (mm)
PL No.		Pharmacode No.		No. of Folds (only for PIL)	
Item Code	L25BAC01/03	Layout No.:			