

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

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.

The name of the medicine is Baclofen 5mg/5ml Oral Solution but will be referred to as 'Baclofen' throughout this leaflet.

What is in this leaflet:

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

1. What Baclofen is and what it is used for

Baclofen belongs to a group of medicines called muscle-relaxant drugs. 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Baclofen

Do not take Baclofen:

Talk to your doctor if

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Baclofen:

- ▶ If you have had a stroke
- ▶ If you suffer from epilepsy
- ▶ If you suffer from any mental illness
- ▶ If you are being treated for high blood pressure
- ▶ If you have Parkinson's disease
- ▶ If you suffer from any liver, kidney or lung disease
- ▶ If you have diabetes
- ▶ If you have difficulties in urinating

- ▶ If you are pregnant or breast feeding
- ▶ If you have a history of alcoholism, 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 are going to have an operation of any kind, make sure that the doctor knows that you are taking this medicine.

Other medicines and Baclofen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

- ▶ Other medicines to relax muscles e.g. tizanidine
- ▶ Medicines to treat mood disorders such as lithium or tricyclic antidepressants such as amitriptyline
- ▶ Medicines for high blood pressure e.g. diltiazem
- ▶ Other drugs which also affect the kidney, e.g. ibuprofen
- ▶ Medicines for Parkinson's disease e.g. levodopa or carbidopa
- ▶ 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).

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

Baclofen with alcohol

Alcohol should be consumed with caution when taking Baclofen, as effects of alcohol may be increased.

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 Baclofen during pregnancy unless your doctor advises you to do so. 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.

Driving and using machines

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

Baclofen contains:

Methyl parahydroxybenzoate (E218): May cause allergic reactions (possibly delayed).

Sorbitol (E420): This medicine contains 1925mg sorbitol in each 5ml dose which is equivalent to 385mg/ml. 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.

Sodium: This medicine contains 8.1mg sodium (main component of cooking/table salt) in each 5ml dose. This is equivalent to 0.41% of the recommended maximum daily dietary intake of sodium for an adult.

Propylene glycol (E1520): This medicine contains 6.675mg propylene glycol in each 5ml dose which is equivalent to 1.335mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take Baclofen

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

Your doctor will tell you how much solution to take each day and when to take it. 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 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.

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

Baclofen should be taken during meals with a little liquid. If you feel sick after taking Baclofen, you may find it helps to take it with food or a milk drink.

Adults

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

Children (0 < 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.

Patients with kidney problems

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

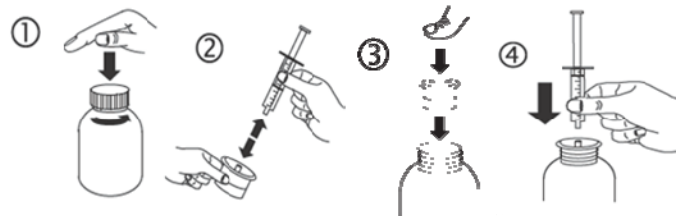
Route and method of administration

This medicinal product must be taken orally.

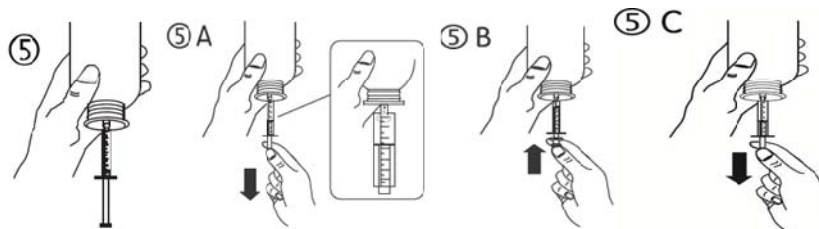
Use the measuring syringes provided in the pack to deliver the required dose.

Instructions for the use of syringe

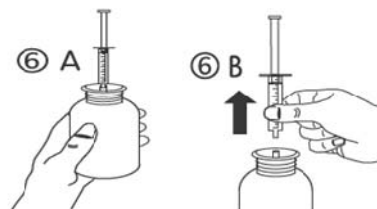
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1).
- b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



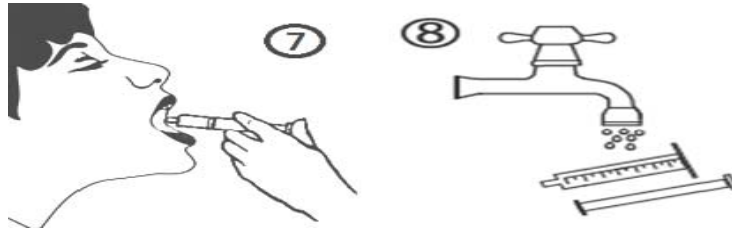
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- e) Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Baclofen than you should

If you accidentally take too much Baclofen, 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

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

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

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: 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 rare: may affect up to 1 in 10,000 people

- ▶ Hypothermia (low body temperature)

Not known: frequency cannot be estimated from the available data

- ▶ Raised itchy rash (urticaria – also known as nettle rash or hives)
- ▶ Slow heart beat
- ▶ Increase in blood sugar
- ▶ Symptoms caused by stopping treatment suddenly (see section 3)
- ▶ Trouble breathing during sleep (sleep apnoea syndrome).

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 HPRA Pharmacovigilance Website: www.hpra.ie.

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

5. How to store Baclofen

- ▶ 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 or bottle after EXP. The expiry date refers to the last day of that month.
- ▶ Do not store above 30°C. Do not refrigerate. Store in the original packaging in order to protect from light.
- ▶ Discard 60 days after first opening.
- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration.
- ▶ Do not throw away any medicine 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 contains

The active substance is baclofen.

Each 5ml of oral solution contains 5mg baclofen.

The other ingredients are methyl parahydroxybenzoate (E218), sorbitol liquid (non-crystallising) (E420), carmellose sodium (E466), raspberry flavour (contains propylene glycol (E1520)) and purified water.

What Baclofen looks like and contents of the pack

Baclofen is clear, pale yellow to yellow coloured oral solution with raspberry flavour supplied in an amber glass bottle with a tamper-evident child resistant plastic cap.

The pack also contains a 1ml oral syringe with 0.01ml graduation marks and 10ml oral syringe with 0.25ml graduation marks and a syringe adaptor.

Baclofen Oral Solution is supplied in bottles containing 300ml oral solution.

POM

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