

Package leaflet: Information for the user
Baclofen 5 mg/5 ml 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, 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
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1. What Baclofen Oral Solution is and what it is used for

The name of your medicine is Baclofen 5 mg/5 ml Oral Solution (referred to as Baclofen Oral Solution in this leaflet). Baclofen Oral Solution contains the active ingredient baclofen, which is a muscle-relaxant.

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 Baclofen Oral Solution

- 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.

If any of the above apply to you, tell your doctor or pharmacist immediately, as Baclofen Oral Solution may not be suitable for you.

Warnings and precautions

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

- 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
- if you are being treated for high blood pressure
- if you have diabetes
- if you have Parkinson's disease
- if you are pregnant or are breast-feeding (see section "Pregnancy and breast-feeding")
- if you have had a stroke
- If you have a history of alcoholism, you drink alcohol to excess or you have a history of drug abuse or dependence.

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 any of the above apply to you or if you are not sure, tell your doctor or pharmacist.

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 any 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 disorders such as lithium or, tricyclic antidepressants such as amitriptyline
- medicines for high blood pressure e.g. diltiazem
- other medicines which also affect the kidney, e.g. ibuprofen
- medicines which slow down the nervous system, e.g. antihistamines such as promethazine, sedatives such as temazepam, opiates for pain relief such as morphine and anti-convulsants (medicines for epilepsy such as carbamazepine)
- medicines for Parkinson's disease e.g. levodopa or carbidopa

Baclofen Oral Solution and alcohol

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

Other special warnings

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.

Whilst you are taking this medicine, your doctor may want to give you a check up from

time to time.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor 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 Oral Solution during pregnancy, your unborn baby will also be exposed to Baclofen Oral Solution. After birth, your baby may develop withdrawal symptoms such as convulsions (symptoms of withdrawal are described in Section 3 “If you stop taking Baclofen Oral Solution”).

Only a very small amount of baclofen passes into breast milk. Your doctor will discuss with you whether you should breast-feed while taking Baclofen Oral Solution.

Driving and using machines

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

Baclofen Oral Solution contains methyl and propyl parahydroxybenzoate and sorbitol

This medicinal product contains:

- Small amounts of the preservatives methyl and propyl parahydroxybenzoate. These can sometimes cause allergic reactions which might appear sometime after first taking the medicine.
- Sorbitol. If you have been told by your doctor that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance, an inborn disease in which a person lacks the protein need to break down fructose, contact your doctor before taking/you are given this medicine. May cause gastrointestinal discomfort and mild laxative effect.

3. How to take Baclofen Oral Solution

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

Recommended dose

In all patients the dose is increased gradually, usually every 3 days, starting with doses of 5-15 mg (5-15 ml) per day. Each dose should be taken during meals with a little liquid. The final dose depends on how you respond. 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.

The usual doses of Baclofen Oral Solution are as follows:

Adults

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

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.

Patients with kidney problems

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

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 Oral Solution than you should

If you realize you have taken too much of your medicine (or if someone else has taken some of your Baclofen Oral Solution), tell your doctor **at once**. If you cannot reach your doctor, contact your nearest hospital casualty department. Take your medicine with you.

Signs of overdose include: ringing in the ears, drowsiness, breathing difficulties, changes in consciousness or coma. Muscle weakness or spasm, confusion, hallucinations, agitation, convulsions, reflex problems, vision problems, enlargement of blood vessels, low or high blood pressure, irregular heart beat, reduced body temperature, nausea, diarrhoea and vomiting, excessive saliva production, increased levels of a blood enzyme and muscle injury may also occur.

If you stop taking Baclofen Oral Solution

You should not stop taking your medicine suddenly.

If the doctor decides to stop your treatment with Baclofen Oral Solution, 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).

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 the forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These occur mainly at the start of treatment, if the dose is increased too quickly or is too high, or in elderly patients. Effects often last only a short time and usually disappear when the dose is reduced. They are not usually severe enough to stop you taking your medicine.

Serious side effects

If you notice any of the following serious side effects, tell your doctor immediately:

- Convulsions (fits), particularly in epileptics,
- Breathing difficulties,
- Excessive weakness of the limbs or feeling tired and exhausted,
- Difficulties in passing urine.

The other side effects listed below have also 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):

- Aching muscles
- Headache, dizziness or light-headedness
- Sleeplessness
- Mood changes, depression, confusion, hallucinations or nightmares
- Dry mouth
- Eye problems (blurred or double vision, difficulty focusing, trembling or flickering 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 (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

- Sexual problems in men, e.g. impotence (often called erectile dysfunction), the inability to achieve or maintain an erection long enough to engage in sexual intercourse.

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.
- Trouble breathing during sleep (sleep apnoea syndrome).
- Symptoms caused by stopping treatment suddenly (see section 3. 'How to take Baclofen Oral Solution').
- Reduction in brain function (encephalopathy)

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 the Yellow Card Scheme (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 Oral Solution

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

Do not use after the expiry date that is stated on the carton and bottle labels after EXP. The expiry date refers to the last day of that month.

Once opened, the solution should be used within 60 days.

Store the solution so that it is protected from light. Do not store above 25°C. Do not put it in the fridge.

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 Oral Solution contains

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

The other ingredients are: methylparahydroxybenzoate (E218), propylparahydroxybenzoate (E216), raspberry flavour, hydroxyethylcellulose (E1525), propylene glycol (E490/E1520), sorbitol (E420), sodium hydroxide and purified water.

What Baclofen Oral Solution looks like and the contents of the pack

Baclofen Oral Solution is a clear, colourless to pale yellow solution with a raspberry flavour, which is available in amber glass bottles with tamper-evident caps.

Each bottle contains 300 ml oral solution.

Each bottle is packed in a carton.

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

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

Manufacturer

Waymade PLC, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, UK

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