

Package leaflet: Information for the user

Baclofen 10 mg Tablets (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 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
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1. What Baclofen Tablets are and what they are used for

Baclofen Tablets contain 10 mg 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 think you may be allergic to baclofen or to any of the other ingredients of the tablets, (these are listed at the end of the leaflet.)
- you have ever had a stomach ulcer.

You should also ask yourself these questions before taking Baclofen Tablets:

- Have you had a stroke?
- Do you have epilepsy?
- Do you suffer from any mental illness?
- Are you being treated for high blood pressure?
- Do you have Parkinson's disease?
- Do you suffer from any liver, kidney or lung disease?
- Do you have diabetes?
- Do you have difficulties in urinating?
- Are you pregnant or breast-feeding? (See section "Pregnancy and breast-feeding").
- Do you have a history of drug abuse or dependence

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

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor or pharmacist 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 that lower blood pressure including medicines used to treat 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 means medicines you have bought yourself as well as medicines on prescription from your doctor.*

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 Baclofen.

Will there be any problems with driving or using machinery?

Some people may feel drowsy and/or dizzy or have problems with their eyes while they are taking Baclofen Tablets. 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.

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 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 Tablets, you may find it helps to take them with food or a milk drink.

Adults

- The usual dose is 20 mg three times a day.
- The maximum daily dose is 100 mg a day.

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 sufficient for the child's individual requirements, this may be between 0.75 and 2 mg/kg body weight. The maximum daily dose should not exceed 2 mg/kg/day. The maximum daily dose should not exceed 40 mg/day in children below 8 years old and 60 mg/day in children 8 years and older.

Patients with kidney problems

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

What if you forget to take a dose?

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

What if you take too much?

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

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:

More than 1 in 10 people have experienced:

Tiredness, sleepiness, nausea (feeling sick).

Up to 1 in 10 people have experienced:

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.

Up to 1 in 1,000 people have experienced:

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 have experienced:

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 heart beat.

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

Symptoms caused by stopping treatment suddenly (see '3. How to take Baclofen Tablets').

Reduction in brain function (encephalopathy)

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 the Yellow Card Scheme Website: 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.

This medicinal product does not require any special storage conditions.

Do not take the tablets after the expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking Baclofen Tablets, please take any which are left back to your pharmacist to be destroyed. Only keep them if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Contents of the pack and other information

What Baclofen contains

The active substance is Baclofen

The other ingredients are microcrystalline cellulose, pregelatinized maize starch, sodium starch glycolate (type A), silica colloidal anhydrous, magnesium stearate

What Baclofen looks like and contents of the pack

White to off white, circular, flat faced beveled edge tablets debossed with “1” and “0” on either side of the breakline one face and plain on other face. The tablet can be divided/split into equal halves.

Baclofen 10 mg Tablets are in white opaque PVC/PVDC-Aluminium blister pack of 84,100 or 200 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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