Title: Baclofen 10mg Tablets

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Date:
05/10/24 *(Modified)* 07/10/25

Size (mm): 200x230

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Process

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Package leaflet:
Information for the patient

Baclofen 10mg 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, please 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 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 are they used for

Baclofen Tablets contain 10 mg of the active substance 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

Do NOT take Baclofen tablets:
- If you are allergic to baclofen or any of the other ingredients of this medicine (listed in Section 6).
- If you 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
- if you suffer from epilepsy
- if you suffer from any mental illness
- if you are being treated for high blood pressure
- if you suffer from Parkinson's Disease
- if you suffer from any liver, kidney or lung disease
- if you have diabetes
- if you have difficulty urinating (urinary retention)
- if you are pregnant or breast-feeding.
- if you have a history of drug abuse or dependence.

Other medicines and Baclofen tablets
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, and herbal preparations.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Other medicines to relax muscles e.g. tizanidine
- Medicines to treat mood disorders e.g. lithium or tricyclic antidepressants such as amitriptyline.
- Medicines for high blood pressure e.g. diltiazem
- Other drugs which 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)

Pregnancy, breast-feeding and fertility
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. 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 Tablets**").

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 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 a lcohol 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

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

The doctor will tell you the best time to take this 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 has a stroke.

If you feel sick after taking Baclofen Tablets, it may help to take them with food or a milk drink.

Adults
- The usual dose is 20 mg (2 tablets) three times a day.
- The maximum daily dose is 100 mg (10 tablets) 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 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. Baclofen Tablets are not suitable for use in children below 33 kg body weight. Other forms of this medicine may be more suitable for children, ask your doctor or pharmacist.

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 to make up for a forgotten dose.

If you take more Baclofen than you should
You should contact your doctor or go to the nearest hospital casualty department straightaway. Take your medicine or the pack with you so that the doctor knows what you have taken. Signs of overdose include drowsiness, breathing difficulties, changes in consciousness or coma. Also muscle weakness or spasm, confusion, hallucinations, agitation, fits, reflex problems, vision problems, enlargement of blood vessels, low or high blood pressure, slow, fast or irregular heartbeat, low body temperature, feeling or being sick, diarrhoea, excessive saliva production, increased blood levels of a liver enzyme, muscle injury, ringing in the ears.

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, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, feeling persecuted or convulsions (fits).

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.

<u>The side effects listed below have been reported:</u>

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.
- Trouble breathing during sleep (sleep apnoea syndrome)
- 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, 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.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Baclofen Tablets

- Keep out of the sight and reach of children.
- Do not take after the expiry date which is stated on the container label and on the carton. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Do not throw it away with your household waste or in water. Return all the unwanted medicine to your pharmacist. This will help to protect the environment.

6. Contents of the pack and other information

What Baclofen Tablets contain
- The active ingredient is Baclofen (10mg). The other ingredients are: Microcrystalline Cellulose, Pregelatinised Starch, Maize Starch and Magnesium Stearate

What Baclofen Tablets look like and contents of the pack
Baclofen 10mg Tablets are white, round, flat, uncoated tablets with a breakline on one side and plain on the other side.

They are available in PVC/PVdC and aluminium blister packs of 28, 84 and 100 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
<u>Marketing Authorisation Holder</u>
RxFarma, Colonial Way, Watford, Hertfordshire, WD24 4YR, UK.

<u>Manufacturer</u>
Rx Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR, UK.

This leaflet was last revised in October 2025

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