Baclofen 10mg tablets

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.

1 What Baclofen tablets are and what they are used for
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 to any of the other ingredients of this medicine (listed in section 6)
- have ever had a stomach ulcer

Warnings and precautions
Talk to your doctor or pharmacist before taking Baclofen tablets if you:
- have had a stroke
- have 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 difficulties urinating
- are pregnant or breast-feeding
- have a history of alcoholism, or you 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. 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.

3 How to take Baclofen Tablets
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.

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

Other medicines and Baclofen Tablets
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 for high blood pressure e.g. diuretics
- 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 (antiepileptic 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

Pregnancy:
Ask your doctor or pharmacist for advice before taking any medicine. You should not take Baclofen tablets 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 tablets 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").

Breastfeeding:

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 tablets.

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 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.
- 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.

Baclofen tablets contain lactose
If you have been told that you have intolerance to some sugars, contact your doctor before taking this medicine.

Tests
- If you are diabetic or have liver disease your doctor may take regular medicines on prescription from your doctor.

4 Possible side effects

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5 How to store Baclofen Tablets

No changes are permitted by any 3rd party other than added notes and mark ups for required changes.
How to take Baclofen Tablets

Your 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 (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 for 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.

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

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 an overdose include drowsiness, breathing difficulties, or contact your nearest hospital casualty department. Take your medicine with you.

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 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 compulsions (fits).

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

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

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

How to store Baclofen Tablets
Keep this medicine out of the sight and reach of children. Store below 25°C and protected from light. Do not use Baclofen tablets after the expiry date stated on the carton after Exp. The expiry date refers to the last day of that month.

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 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.

Contents of the pack and other Information
What Baclofen tablets contain
• The active substance (the ingredient that makes the tablet work) is baclofen. Each tablet contains 10mg of the active ingredient
• The other ingredients are lactose, pregelatinised maize starch, magnesium stearate, water.

What Baclofen tablets look like and contents of the pack
Baclofen Tablets 10mg are white to off-white, circular, biconvex uncoated tablets impressed “C” on one face, and the identifying letters “B” “L” on either side of a central division line on the reverse.

Pack size is 84 tablets.

Marketing Authorisation Holder and Manufacturer
Accord, Barnstable, EX32 8NS, UK.

This leaflet was last revised in November 2020