PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Baclofen Tablets 10mg
(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 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 Tablets contain the active substance baclofen, which is a muscle-relaxant drug.

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.

2. What you need to know before you take Baclofen

Do not take Baclofen:
- if you are allergic to baclofen or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include rash, itching and swelling of the face, lips, throat or tongue
- if you have ever had a stomach ulcer.

Warnings and precautions
Talk to your doctor or pharmacist before taking Baclofen:
- if you suffer from a mental disorder
- if you suffer from liver or kidney disease
- if you have breathing difficulties or lung disease
- if you have diabetes as your doctor may want to monitor your condition
- if you have suffered from a stroke
- if you suffer from epilepsy
- if you have difficulty urinating (urinary retention)

- if you suffer from Parkinson's disease
- if you being treated for high blood pressure
- if you are pregnant or breast-feeding
- if you have a history of alcoholism, or your 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 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.

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 when you will have a general anaesthetic, tell the doctor or dentist that you are taking Baclofen.

Your doctor may do regular blood tests to monitor your liver function.

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

Other medicines and Baclofen
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must tell your doctor if you are already taking any of the following medicines:
- other medicines to relax muscles e.g. tizanidine
- medicines to treat mood disorders such as lithium or tricyclic depressants such as amitriptyline
- medicines for high blood pressure e.g. diltiazem
- medicines which affect the kidney, e.g. ibuprofen
- medicines for Parkinson's disease e.g. levodopa and carbidopa
- medicines which slow down the nervous system, such as anti-histamines (e.g. promethazine), sedatives (e.g. temazepam), opiates for pain relief (e.g. morphine, fentanyl) and anti-epileptic medicines (e.g. carbamazepine).

Baclofen with alcohol
Do not drink alcohol whilst taking Baclofen.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Baclofen during pregnancy unless your doctor tells you otherwise.

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").

Although very small amounts of Baclofen pass into breast milk, your doctor will discuss with you whether you should breast-feed whilst taking this medicine.

Driving and using machines
Some people may feel drowsy and/or dizzy or have problems with their eyes while they are taking these 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.

Baclofen contains lactose and sodium

This medicine contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Baclofen

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

You will be started on a low dose and this will be increased gradually over a few days, under the supervision of 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.

Adults
The recommended dose is 5 mg Baclofen (half a tablet) 3 times a day for 3 days, then

- 10 mg Baclofen (1 tablet) 3 times a day for the next 3 days, then
- 15 mg Baclofen (one and half tablets) 3 times a day for 3 days, then
- 20 mg Baclofen (2 tablets) 3 times a day for the next 3 days.

The maximum daily dose is 100 mg except if you are in hospital when a higher dose may be used.

Elderly patients
Elderly patients will usually start with a smaller daily dose of Baclofen.

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

Use in children and adolescents
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.

How to take the tablets
You should take the tablets with food or a milk drink, especially if you feel sick when you take them. Baclofen may be taken just at night-time to help painful night cramps or approximately 1 hour before doing specific tasks such as washing or physiotherapy, which are helped by taking Baclofen. Your doctor will tell you what is best for you.

If you take more Baclofen than you should
If you take more Baclofen than you have been prescribed, contact your doctor or local hospital immediately. You may experience ringing in the ears. Take the medicine with you.

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 to make up for a forgotten dose.

If you stop taking Baclofen
Do not stop taking Baclofen suddenly unless your doctor tells you. If you stop taking your Baclofen Tablets without gradually reducing the dose you may suffer from unpleasant side effects such as muscle spasms and increased muscle rigidity, fast heart rate, fever, hallucinations, changes in mood and emotion, confusion, 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.

If you have breathing difficulties, stop using baclofen and tell your doctor or go to your nearest hospital emergency room immediately as you may need urgent medical treatment

Other side effects include:

Very Common (may affect more than 1 in 10 people)
- drowsiness
- sleepiness
- feeling sick.

Common (may affect up to 1in 10 people)
- dry mouth
- headache, dizziness or light-headedness
- fatigue
- excessively weak limbs or feeling tired and exhausted, aching muscles
- unsteadiness, trembling or other problems with muscle control
- confusion, depression
- mood changes with extreme excitement,
- hallucinations (seeing or feeling or hearing things that are not really there) or nightmares,
- low blood pressure (fainting)

- stomach upset including retching, vomiting, diarrhoea or constipation
- sleeplessness
- skin rash, excessive sweating
- rapid, uncontrollable movements of the eyes or other eyesight problems
- pain when passing urine or passing more urine than normal

Rare (may affect up to 1 in 1,000 people)
- numbness or pins and needles in hands or feet
- increased muscle spasm
- slurred or slow speech
- disturbed sense of taste
- stomach pain
- difficulty passing urine,
- problems getting or keeping an erection
- liver problems. Your doctor may do regular blood tests to monitor your liver function

Very rarely (may affect up to 1 in 10,000 people)
- low body temperature (hypothermia).

Not known (frequency cannot be estimated from available data)
- raised, itchy rash ('nettle rash')
- slow heart beat
- increase in blood sugar
- trouble breathing during sleep (sleep apnoea syndrome)
- reduction in brain function (encephalopathy)
- swelling of the ankles, feet or lower legs
- swelling face
- allergic reaction (hypersensitivity)
- hair loss
- sexual difficulties
- symptoms caused by stopping treatment suddenly (see 'How to take Baclofen Tablets')

If have epilepsy you may experience more convulsions than usual.
If you are elderly or if you have mental problems or you have suffered from a stroke, the side effects may be more serious.

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 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

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 after "EXP". The expiry date refers to the last day of that month.

Store in a dry place below 25°C. Protect from light.

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 protect the environment.

6. Content of the pack and other information

What Baclofen contains

- The active substance is baclofen. Each tablet contains 10 mg of baclofen.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, calcium phosphate, silica, magnesium stearate and sodium starch glycollate.

What Baclofen looks like and contents of the pack

Baclofen tablets are flat bevelled edge tablets marked "BN" breakline "10" on one side and "G" on the reverse.

Baclofen Tablets are available in containers of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250 or 500 tablets and in blister packs of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168 and 180 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer:
Mylan Hungary Kft.,
Mylan utca 1.,
Komárom,
2900,
Hungary.

Or

Mylan Laboratories SAS
Route de Belleville,
lieu-dit Maillard,
Chatillon Sur Chalaronne,
01400,
France

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