Package Leaflet: Information for the patient

Baclofen 5 mg Tablets
Baclofen 10 mg Tablets
Baclofen 20 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 are they 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. Content of the packs and other information

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)
- if you have ever had a stomach ulcer

Warnings and precautions
Talk to your doctor or pharmacist before taking Baclofen Tablets if the answer to any of these questions is YES. This is because Baclofen Tablets might not be the right medicine for you:

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

There have been reports of reduction in brain function (encephalopathy) in some patients taking Baclofen Tablets 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.

Your doctor may do regular blood tests to monitor your liver function while you are taking Baclofen Tablets.

Children and adolescents
Baclofen Tablets are not suitable for use in children below 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 antidepressants such as amitriptyline
- medicines for high blood pressure e.g. diltiazem
- other medicines 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. antihistamines 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.*

Baclofen with alcohol
Be careful when drinking alcohol – it may affect you more than usual.

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

You should not use Baclofen Tablets during pregnancy unless your doctor advises you to do so.

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**").

Only a very small amount of baclofen tablets 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 operate tools or machinery) until these effects have worn off.

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.
- 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.

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 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 Tablets 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 recommended starting dose is 15 mg per day (5 mg three times a day). Depending on your individual requirement the doctor may gradually increase the dose up to 60 mg per day (20 mg three times a day).

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.

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 overdoses are: ringing in the ears

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 stop taking Baclofen Tablets
Do 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.

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, depression, 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 available data

- Raised, itchy rash (urticaria – also known as nettle rash or hives)
- Slow heartbeat
- Increase in blood sugar
- Trouble breathing during sleep (sleep apnoea syndrome)
- Symptoms caused by stopping treatment suddenly (see section '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 side-effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effect not listed in this leaflet. You can also report side effects directly via 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 out of sight and reach of children.

Store below 25ºC. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton, blister or bottle label after "EXP". The expiry date refers to the last day of that month.

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 packs and other information

What Baclofen tablets contains

Each tablet contains 5 mg, 10 mg or 20 mg of the active ingredient, baclofen.

The other ingredients are microcrystalline cellulose, silica colloidal anhydrous, maize starch, povidone K-30, magnesium stearate, and purified water.

What Baclofen Tablets look like and contents of the pack

Baclofen 5 mg Tablets are white to off-white colored, round shaped flat tablets, debossed with B5 on one side, and plain on the other side.

Baclofen 10 mg Tablets are white, round shaped flat tablets, debossed with 'B' and '10' separated by a score line on one side, and plain on the other side.

Baclofen 20 mg white to off-white colored, round shaped flat tablets, debossed with 'B' and '20' separated by by break line on one side, and plain on the other side.

Baclofen Tablets are packaged in blister packs of clear PVC film and aluminium foil as the lidding foil coated with VMCH. The tablets available in packs of 7, 10, 14, 28, 30, 56, 60, 84, 100. 5 mg and 10 mg tablets are also available in packs of 200.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Mercury Pharmaceuticals Limited
Dashwood House,
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Manufacturer:
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