

## Baclofen 10 mg Tablets baclofen

### Package leaflet: Information for the user

**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

Your doctor has decided that you or your child needs this medicine to help treat your condition.

Baclofen is a muscle relaxant that acts on the central nervous system.

Baclofen Tablets are used:

- to treat muscle rigidity caused by brain injury
- to reduce and relieve cramping, muscle rigidity, the excessive tension in your muscles (spasms) occurring in various illnesses such as cerebral palsy, multiple sclerosis, cerebrovascular accidents, spinal cord diseases, injuries to the spinal cord and other nervous system disorders.

Your doctor may sometimes prescribe these tablets for other reasons. If you have any questions ask your doctor or pharmacist for information.

## 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)
- suffer from stomach ulcers.

**Children and adolescents:**

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

**Warnings and precautions:**

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.

**Talk to your doctor or pharmacist before taking Baclofen if you:**

- suffer from schizophrenia, psychotic, depressive or manic disorders (any mental illness)
- suffer from Parkinson's disease
- suffer from confusion
- suffer from epilepsy
- have had a stroke
- suffer from liver or kidney problems
- have Diabetes Mellitus
- suffer from heart problems or have breathing difficulties due to weak muscles. Your doctor will want to carefully monitor your treatment
- suffer from porphyria
- have problems with your bladder muscles (difficulty urinating)
- are pregnant or breast-feeding (see section 2: Pregnancy and breast-feeding)
- have a history of alcoholism, 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. 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.

### Other medicines and Baclofen

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

Talk to your doctor or pharmacist if you are taking any of the following:

- other medicines to relax muscles e.g. tizanidine
- drugs to lower your blood pressure, including ACE inhibitors e.g. captopril
- tricyclic antidepressants e.g. amitriptyline, clomipramine, dothiepin or dosulepin
- medicines for high blood pressure e.g. diltiazem
- drugs which also affect the kidney such as ibuprofen
- lithium
- levodopa plus carbidopa, for Parkinson's Disease
- synthetic opiates e.g. dihydrocodeine or tramadol
- 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).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### Baclofen with food and alcohol

You should be aware that taking alcohol with Baclofen may cause drowsiness.

### 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.

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.

### Driving and using machines

Baclofen may cause drowsiness, decreased alertness, dizziness, incoordination, and shaking. If you are affected, do not drive or operate machinery.

### Important information about some of the ingredients of Baclofen

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23mg) 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.

The tablets should be swallowed preferably with a drink of water. 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. The timing and usual range of doses is:

#### • Adults

The dosage you receive will gradually be increased until your condition is under adequate control. The dosage schedule given below is only a guide and may vary from person to person.

- Start with 5 mg three times a day for three days
- Then 10 mg three times a day for the next three days
- Then 15 mg three times a day for the next three days
- Finally 20 mg three times a day for three days.

The usual maintenance dose is 20 mg three times a day (60 mg a day). The maximum dose is 100 mg a day.

• **Use in children and adolescents (0 to <18 years)**  
Children's treatment is adjusted to their body

weight. Children's treatment usually starts with 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.

• **Elderly**

You may be more likely to suffer from side effects, especially at the start of treatment. Therefore, your doctor may start you on a lower dose than the usual adult dosage.

• **Patients with kidney problems**

You may be started on a lower dose of Baclofen e.g., 5 mg a day. The doctor will decide what the dose should be.

**If you take more Baclofen than you should**

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause coma, drowsiness, loss of consciousness, breathing problems and ringing in the ears.

Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

**If you forget to take Baclofen**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do NOT take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.

**If you stop taking Baclofen**

Do NOT stop taking Baclofen without talking to your doctor first even if you feel better. Do NOT stop taking your tablets suddenly because unwanted effects such as muscle spasms and increased muscle rigidity, difficulty in controlling movement, fast heart rate, fever, confusion, hallucinations, changes in mood and emotion, mental disorders, anxiety, manic or paranoid state, or fits may occur. Your doctor will reduce your dose gradually.

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. Side effects may be more serious in patients with a history of psychiatric illness, stroke and in the elderly.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

You may notice the following side effects when you first start taking Baclofen, but they may lessen as you get used to your medicine or if the dose is reduced:

- daytime drowsiness
- feeling sick.

If the feeling of sickness continues after your dosage has been decreased, it may be lessened by taking Baclofen with food or milk. Discuss this with your doctor.

The following side effects have been reported at the approximate frequencies shown:

**Very common** (may affect more than 1 in 10 people):

- drowsiness and sleepiness
- feeling sick (nausea).

**Common** (may affect up to 1 in 10 people):

- nightmares
- light-headedness
- shallow breathing
- exhaustion or lack of energy
- dizziness
- headache
- reduced heart function
- low blood pressure
- confusion
- difficulty in sleeping
- changes in mood
- muscle weakness and pain

- hallucinations
- dry mouth
- loss of co-ordination
- shaking
- difficulty focusing and controlling eye movements
- skin rash
- excessive sweating
- retching, being sick, constipation, diarrhoea or stomach problems
- needing to pass water often
- pain or difficulty passing water
- incontinence.

**Rare** (may affect up to 1 in 1,000 people):

- speech disorder
- pins-and-needles
- unusual taste sensations
- abdominal pain
- impotence (inability to get or maintain an erection)
- inability to pass water
- abnormal liver function leading to changes in blood sugar or blood levels of certain liver enzymes.

**Very rare** (may affect up to 1 in 10,000 people)

- hypothermia (low body temperature).

**Not known** (cannot be estimated from available data)

- nettle rash
- trouble breathing during sleep (sleep apnoea syndrome)
- fits (particularly in epileptics)
- slow heartbeat
- increase in blood sugar
- sexual difficulties
- symptoms caused by stopping treatment suddenly
- reduction in brain function (encephalopathy).
- allergic reaction (hypersensitivity)
- hair loss (alopecia)
- swelling of the ankles, feet or lower legs
- swelling face.

Some patients have experienced an unexpected (paradoxical) increase in involuntary muscle stiffness (spasticity).

**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 at: [www.mhra.gov.uk/yellowcard](http://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 that is stated on the carton after "EXP". The expiry date refers to the last day of that month.

Store in a dry place at or below 25°C. Store in the original package.

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 Contents of the pack and other information**

**What Baclofen tablets contains**

- The active substance is baclofen.
- The other ingredients are lactose, microcrystalline cellulose, sodium starch glycolate and magnesium stearate.

**What Baclofen tablets look like and contents of the pack:**

- Baclofen 10 mg Tablets are white, plain, flat bevel-edged tablets. They are marked breakline and '3K2'
- Baclofen 10 mg Tablets are available in pack sizes of 10, 28, 30, 50, 56, 60, 84, 100, 250, 500, or 1000. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

**Manufacturer**

TEVA Pharmaceutical Works Private Limited Company, Debrecen, Pallagi út 13, H-4042, Hungary

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