

BACLOFEN 10 mg TABLETS

baclofen

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What Baclofen is and what it is used for
2. Before you take Baclofen
3. How to take Baclofen
4. Possible side effects
5. How to store Baclofen
6. Further information

1 WHAT BACLOFEN IS AND WHAT IT IS USED FOR

Please read this product information carefully before you or your child is given Baclofen since it contains important information.

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 this medicine for other reasons. If you have any questions ask your doctor or pharmacist for information.

2 BEFORE YOU TAKE BACLOFEN

Do NOT take Baclofen if you:

- are allergic/hypersensitive to baclofen or any of the other ingredients in this medicine (these are listed with the name of the tablet).
- suffer from stomach ulcers.

Children and adolescents:

Baclofen tablets are not suitable for use in children under 25 kg body weight.

Talk to your doctor about Baclofen

Before you start to take this medicine if you:

- suffer from schizophrenia, psychosis, depression or mental disorders (any mental illness)
- suffer from Parkinson's disease
- suffer from confusion
- suffer from epilepsy
- have liver problems
- suffer from liver or kidney problems
- have diabetes mellitus
- suffer from heart problems or have a heart failure
- have difficulty or trouble with 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).

Take your medicine

Take your medicine exactly as your doctor has told you. Your doctor will tell you exactly how long you should take this medicine. You should check this with your doctor or pharmacist if you are not sure.

to follow:

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

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

Taking Baclofen with food and drink

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

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking any medicine.

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

Patients who are intolerant to lactose should note that Baclofen tablets contain a small amount of 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.

3 HOW TO TAKE BACLOFEN

Always take Baclofen exactly as your doctor has told you. Your doctor will tell you exactly how long you should take this medicine. You should check this with your doctor or pharmacist if you are not sure.

The tablets should be swallowed whole with a drink of water at the time of a usual range of doses as follows:

- Use in children (0 to <25 kg body weight): Children's treatment is adjusted to their body weight. Children's treatment usually starts with very low doses (approximately 0.3 mg/kg/day), in 2-4 divided doses preferably in 4 doses. The doses are then gradually increased until the doses are sufficient for the child's individual requirements. This may be between 0.45 and 2 mg/kg body weight. The total daily doses should not exceed a maximum of 40 mg/day in children below 15 years of age and children over 15 years of age a maximum daily dose of 60 mg/day may be given. Baclofen tablets are not suitable for use in children below 25 kg body weight.

Adults

- The dosage you receive will gradually be increased until your condition is under adequate control. The dosage should be given below the usual guidelines and may vary from person to person.
- Start with 10 mg three times a day for three days
- Then 10 mg three times a day for three next three days
- Then 15 mg three times a day for three next three days
- Finally 20 mg three times a day for three days.

The usual maintenance doses are 20 mg three times a day, 30 mg three times a day or 40 mg three times a day.

