

BACLOFEN 10 mg TABLETS baclofen

PACKAGE LEAFLET: INFORMATION FOR THE USER

- Read all of the information 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:

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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 to help with other conditions. If you have any questions ask your doctor or pharmacist for more information.

2 BEFORE YOU TAKE BACLOFEN

Do NOT take Baclofen if you:

- are allergic 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 20 kg body weight.

Take special care with Baclofen

Tell your doctor 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 constipation
- 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 breathing or weak muscles. Your doctor will warn you carefully about 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).

Inform your doctor if you are taking any of the following:

- 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 with your doctor or pharmacist if you are not sure.

The total dose should be given in 4 equal doses with a drink of water at the following usual ranges of doses:

- **Children under 10 to 20 kg body weight:** 10 mg 4 times a day. The total daily dose is 40 mg.
- **Children 20 to 30 kg body weight:** 15 mg 4 times a day. The total daily dose is 60 mg.
- **Children 30 to 40 kg body weight:** 20 mg 4 times a day. The total daily dose is 80 mg.
- **Children 40 to 50 kg body weight:** 25 mg 4 times a day. The total daily dose is 100 mg.
- **Children 50 to 60 kg body weight:** 30 mg 4 times a day. The total daily dose is 120 mg.
- **Children 60 to 70 kg body weight:** 35 mg 4 times a day. The total daily dose is 140 mg.
- **Children 70 to 80 kg body weight:** 40 mg 4 times a day. The total daily dose is 160 mg.
- **Children 80 to 90 kg body weight:** 45 mg 4 times a day. The total daily dose is 180 mg.
- **Children 90 to 100 kg body weight:** 50 mg 4 times a day. The total daily dose is 200 mg.

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 4 times a day for three days
- Then 15 mg 4 times a day for three to five days
- Then 20 mg 4 times a day for three to five days
- Then 25 mg 4 times a day for three to five days
- Then 30 mg 4 times a day for three to five days
- Then 35 mg 4 times a day for three to five days
- Then 40 mg 4 times a day for three to five days
- Then 45 mg 4 times a day for three to five days
- Then 50 mg 4 times a day for three to five days

The usual maintenance doses are 20 mg 4 times a day (80 mg daily) or 30 mg 4 times a day (120 mg daily).

	<p>• Elderly</p> <p>...with they will affect ...</p>	<p>• low blood pressure</p> <p>...common on ...</p> <ul style="list-style-type: none"> • 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 • stomach problems • needing to pass water often • pain or difficulty passing water • incontinence. <p>Uncommon (affecting less than one person in more than one person in 1,000):</p> <ul style="list-style-type: none"> • speech disorder
ments	<p>If you take more Baclofen than you should</p> <p>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 and breathing problems. 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.</p>	
or	<p>If you forget to take Baclofen</p> <p>If you forget to take a tablet, take one as soon as you remember. Do not take two tablets to make up for a missed one. Do not stop taking Baclofen without talking to your doctor first, even if you feel better.</p>	
100 but	<p>If you stop taking Baclofen</p> <p>Do NOT stop taking Baclofen without talking to your doctor first, even if you feel better.</p>	
	<p>4 POSSIBLE SIDE EFFECTS</p> <p>Like all medicines, Baclofen 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.</p> <p>If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:</p> <ul style="list-style-type: none"> • an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives). <p>This is a very serious, but rare side effect. You may need urgent medical attention or hospitalisation.</p> <p>You may not see 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:</p> <ul style="list-style-type: none"> • daytime drowsiness • feeling sick. <p>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.</p> <p>The following side effects have been reported at the approximate frequencies shown:</p> <p>Very common (affecting more than one person in 10):</p> <ul style="list-style-type: none"> • drowsiness and sleepiness • feeling sick (nausea). <p>Common (affecting less than one person in 10 but more than one person in 100):</p> <ul style="list-style-type: none"> • nightmares • light-headedness • shallow breathing • exhaustion or lack of energy • dizziness • headache • reduced heart function 	
		<p>5 HOW TO STORE BACLOFEN</p> <p>Keep out of the reach and sight of children. Store in a dry place at or below 25°C in the package or container supplied. Do not transfer them to another container. Do not use Baclofen after the expiry date that is shown on the outer packaging. The expiry date refers to the last day of that month.</p> <p>Medicines should not be disposed of as a household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.</p>
		<p>6 FURTHER INFORMATION</p> <p>What Baclofen tablets contain:</p> <ul style="list-style-type: none"> • The active ingredient is baclofen • The other ingredients are lactose, microcrystalline cellulose, sodium starch glycolate and magnesium stearate. <p>What Baclofen tablets look like and contents of the pack:</p> <ul style="list-style-type: none"> • Baclofen 10 mg Tablets are white, plain, flat, bevel-edged tablets. They are marked breakline '3K2' • Baclofen 10 mg Tablets are available in pack sizes 10, 28, 30, 50, 56, 60, 84, 100, 250, 500, or 1000. Not all pack sizes may be marketed. <p>Marketing Authorisation Holder and Manufacturer</p> <p>Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG.</p> <p>This leaflet was last revised: March 2011 PL 00289/0243</p>
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