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, pharmacist or nurse.
- 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, pharmacist or nurse. 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 they are 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. Contents of the pack and other information

**What Baclofen tablets are and what they are used for**

Baclofen belongs to a group of medicines called muscle relaxants. These medicines work by acting on the central nervous system and may be used for the relief of muscle spasms, cramping or tightness caused by diseases such as:

- cerebral palsy
- diseases of the spinal cord
- meningitis
- motor neurone disease
- multiple sclerosis
- cerebrovascular accidents
- other injuries or diseases which affect the brain and nervous system.

**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)
- currently have a stomach ulcer
- have porphyria (an inherited condition causing skin blisters, abdominal pain and brain or nervous system disorders).

**Children and adolescents**

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

**How to take Baclofen Tablets**

**Possible side effects**

**How to store Baclofen Tablets**

**Contents of the pack and other information**

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Baclofen tablets if you have

- problems with your lungs, heart, liver, kidney or bladder
- mental illness as Baclofen tablets may make some of the symptoms worse or cause new ones
- ever had stomach ulcers
- epilepsy: may make the fits worse
- ever suffered any bleeding in the brain (a "stroke")
- diabetes mellitus
- been taking any medicines for high blood pressure
- muscle tension in the bladder.

**Other medicines and Baclofen Tablets**

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

- anxiolytics or hypnotics (to help you sleep), taking these medicines with Baclofen could make you very sleepy
- medicines to lower high blood pressure or diuretics (water tablets) as these could lower your blood pressure too much
- levodopa (to treat Parkinson's Disease), may cause worsening of side effects
- lithium (for depression), may aggravate symptoms of over activity
- NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) such as ibuprofen, may cause baclofen to be removed from the body more slowly
- tricyclic antidepressants (eg amitriptyline or imipramine), may cause an increase in the muscle relaxant effect
- memantine (used in alzheimer's disease), effects of Baclofen may be changed
- anaesthetics, if you need an operation, tell your doctor or dentist you are taking Baclofen tablets.

**Baclofen and alcohol**

Do not drink alcohol while you are taking Baclofen tablets. Alcohol may increase the sedative effects of Baclofen tablets and make you very sleepy.

**Pregnancy and breast-feeding**

You should not take Baclofen tablets if you are pregnant, planning to become pregnant or are 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.

**Driving and using machines**

Baclofen tablets may make you feel drowsy, dizzy or light-headed or less alert. Do not drive or use any tools or machines if you are affected in this way.

**Baclofen tablets contains lactose**

If you have been told that you have intolerance to some sugars contact your doctor before taking this medicine.

**Tests**

If you are diabetic or have liver disease your doctor may take regular blood tests. As Baclofen tablets may cause certain blood levels to rise.

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**Baclofen Tablets 10mg x 84's (UK)**

- JDE No.: 50942101
- Component: Leaflet for Blister
- Pharmacode: 3967
- Date Sent: 25/09/17
- Technologist: R.Wrey
- Approved for print/date: 25/09/17

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How to take Baclofen Tablets

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

Swallow the tablets whole, with a glass of water. If you feel sick you may find taking baclofen with a milky drink or with food makes you feel better.

The recommended dose is

- **Adults:** 5mg three times a day gradually increasing up to 20mg three times a day. In some cases your doctor may decide on a dose of up to 100mg a day.
- **If you suffer from painful muscle spasms your doctor may recommend that you take baclofen as a single dose at night. Alternatively it may be recommended you take baclofen one hour before performing specific tasks, such as shaving or dressing, to improve your mobility.
- **Elderly:** Your doctor may give you a smaller dose
- **Children:** Treatment should be calculated according to body weight and given in 2-4 divided doses. Your doctor may increase the dosage slowly to reach the appropriate dose. A more appropriate dosage form may also be used.
- **Children below 8 years of age:** The maximum daily dose should not exceed 0.5mg per kg body weight.
- **Children above 8 years of age:** The maximum daily dose should not exceed 0.5mg per kg body weight.
- **Patients with kidney problems:** Your doctor may give you a smaller dose such as 5mg a day.

If you take more Baclofen tablets than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Signs of an overdose include drowsiness, breathing difficulties, changes in consciousness or coma (unravelling unconsciousness). Also muscle weakness or spasm, confusion, hallucinations, agitation, fits, low blood pressure, slow heart beat, feeling or being sick, dizziness, excessive saliva production, reflex problems.

If you forget to take Baclofen tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

If you stop taking Baclofen tablets

Do not stop taking your medicine without telling your doctor as he may wish to gradually reduce the number of tablets you take before stopping them completely. If you stop taking Baclofen tablets suddenly, you may experience unpleasant side effects including anxiety, confusion, hallucinations, convulsions, unusual behaviour, fast heart beat and temporary worsening of the condition being treated.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Possible Side Effects

Like all medicines, Baclofen tablets can cause side-effects, although not everybody gets them.

**Tell your doctor** if you notice any of the following side effects or notice any other effects not listed:

- allergic reaction: skin rashes
- nervous system: sedation during the day, drowsiness, confusion, depression, insomnia, light-headedness, euphoria (extreme sense of wellbeing), hallucinations, nightmares, headache, dizziness, exhaustion, unusual tiredness or weakness, 'pins and needles', fits, involuntary eye movements, difficulty focusing
- stomach: feeling or being sick, retching, constipation, diarrhoea, dry mouth, changes in taste
- muscles: muscle pain or weakness, lack of muscle control or muscle tension, tremor, irregular and jerky movements, increase in spastic symptoms
- other: changes in the liver function (shown by a blood test), excessive sweating, shallow heartbeat, visual disturbances, low blood pressure, frequent or painful passing of urine, bed wetting, difficulty breathing, trouble breathing during sleeping (sleep apnoea syndrome) (frequency cannot be estimated from the available data), low body temperature (hypothermia).

Withdrawal symptoms: see Section 3, ‘If you stop taking Baclofen tablets.’

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 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.

How to store Baclofen Tablets

Keep this medicine out of the sight and reach of children. Store below 25°C and protected from light.

Do not use Baclofen tablets after the expiry date stated on the carton 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.

Contents of the pack and other information

What Baclofen tablets contain

- The active substance (the ingredient that makes the tablet work) is baclofen. Each tablet contains 10mg of the active ingredient
- The other ingredients are lactose, pregelatinised maize starch, maize starch, magnesium stearate, water.

What Baclofen tablets looks like and contents of the pack

Baclofen tablets are white to off-white, uncoated tablets.

Pack sizes are 84 tablets.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised November 2017.

Baclofen Tablets 10mg x 84’s (UK)

JDE No.: 50942101

Dimensions: 148x210 (Reel Fed)

Component: Leaflet for Blisters

Pharmacode: 3967

Date Sent: 25/09/17

Technologist: R. Wrey

Technically Approved

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.