

Teva Pharmaceuticals (Pty) Ltd.

TEVA BACLOFEN 10, tablets

Each tablet contains 10 mg baclofen

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

TEVA BACLOFEN 10, tablets

Baclofen

Contains sugar (lactose monohydrate 65,2 mg per tablet)

Read all of this leaflet carefully before you are given TEVA BACLOFEN 10:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TEVA BACLOFEN 10 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What TEVA BACLOFEN 10 is and what it is used for
2. What you need to know before you take TEVA BACLOFEN 10
3. How to take TEVA BACLOFEN 10
4. Possible side effects
5. How to store TEVA BACLOFEN 10
6. Contents of the pack and other information

1. What TEVA BACLOFEN 10 is and what it is 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

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caused by conditions such as:

- multiple sclerosis
- diseases of the spinal cord
- other injuries or diseases which affect the brain and nervous system.

2. What you need to know before you take TEVA BACLOFEN 10:**Do not take TEVA BACLOFEN 10:**

- if you are hypersensitive (allergic) to baclofen or any of the other ingredients of TEVA BACLOFEN 10 (listed in section 6).
- if you are pregnant or breastfeeding your baby.
- If you suffer from a condition known as porphyria

Warnings and precautions:**Take special care with TEVA BACLOFEN 10:**

Check with your doctor or pharmacist before taking TEVA BACLOFEN 10 if you:

- have a history of drug abuse or dependence
- suffer from any issues with your posture and balance
- suffer from Parkinson's disease
- suffer from problems with your kidneys, as your doctor may need to reduce your dosage
- suffer from a mental illness as TEVA BACLOFEN 10 may make some of the symptoms worse or cause new ones
- suffer from epilepsy, as TEVA BACLOFEN 10 may make the fits worse
- are taking any medicines for depression, bipolar mood disorder, high blood pressure, or any other medicines which act on your central nervous system
- have stomach ulcers

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- suffer from urinary problems
- suffer from diabetes mellitus
- suffer from liver problems, respiratory failure or cerebrovascular disease (conditions that affect blood flow and the blood vessels in the brain)

Some people being treated with TEVA BACLOFEN 10 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 TEVA BACLOFEN 10:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

- Other medicines to relax muscles e.g., tizanidine
- Medicines for high blood pressure
- Medicines for Parkinson's disease e.g., levodopa or carbidopa
- Medicines to treat mood disorders such as lithium or tricyclic antidepressants used to treat depression
- Opioids (painkillers), which may increase sedation

Taking TEVA BACLOFEN 10 with alcohol:

Drinking alcohol whilst taking TEVA BACLOFEN 10 may make you feel more sleepy. It is recommended not to drink alcohol while you're taking TEVA BACLOFEN tablets.

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TEVA BACLOFEN 10 with food and drink:

TEVA BACLOFEN 10 should be taken during meals with a little liquid.

Pregnancy and breastfeeding and fertility:

TEVA BACLOFEN 10 should not be used during pregnancy.

The safety of using TEVA BACLOFEN 10 while pregnant or breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking TEVA BACLOFEN 10.

Fertility

No data on the effect of TEVA BACLOFEN 10 on human fertility is available.

Driving and using machines

TEVA BACLOFEN 10 may cause drowsiness, dizziness, increased sleepiness, visual disturbances and impair your concentration

Do not drive or operate machinery until you know how TEVA BACLOFEN 10 affects you.

It is not always possible to predict to what extent TEVA BACLOFEN 10 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in driving or use machines until they are aware of the measure to which TEVA BACLOFEN 10 affects them.

Important information about some of the ingredients of TEVA BACLOFEN 10:

TEVA BACLOFEN 10 contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TEVA BACLOFEN 10.

3. How to take TEVA BACLOFEN 10:

Do not share medicines prescribed for you with any other person.

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Always take TEVA BACLOFEN 10 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you have the impression that the effect of TEVA BACLOFEN 10 is too strong or too weak, talk to your doctor or pharmacist.

The final dose of TEVA BACLOFEN 10 depends on how each person responds to the medicine. 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 no benefit is apparent within 6 to 8 weeks of achieving the maximum dosage, a decision whether to continue with TEVA BACLOFEN 10 should be taken.

If you feel sick after taking TEVA BACLOFEN 10 tablets, you may find it helps to take them with food or a milk drink.

Adults:

The recommended dose is 5 mg TEVA BACLOFEN 10 (half a tablet) 3 times a day for 3 days, then

- 10 mg Baclofen (1 tablet) 3 times a day for the next 3 days, then
- 15 mg Baclofen (one and half tablets) 3 times a day for 3 days, then
- 20 mg Baclofen (2 tablets) 3 times a day for the next 3 days.

The maximum daily dose ranges from 30 to 80 mg daily.

Children (0 to < 18 years):

Treatment should usually be started with a very low dose, e.g. 0,3 mg/kg a day, in divided doses. The dosage should be raised cautiously, at about 1 to 2 week intervals, until it becomes sufficient for the child's individual

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requirements. The usual daily dosage for maintenance therapy ranges between 0,75 and 2 mg/kg body mass. In children over 10 years of age, however, a maximum daily dosage of 2,5 mg/kg body mass may be given.

Patients with kidney problems:

You will probably be given a much lower dose. The doctor will decide what the dose should be.

Your doctor will tell you how long your treatment with TEVA BACLOFEN 10 will last. If you have the impression that the effect of TEVA BACLOFEN 10 is too strong or too weak, tell your doctor or pharmacist.

If you take more TEVA BACLOFEN 10 than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine with you.

Signs and symptoms may include:

- drowsiness
- impaired concentration, confusion or hallucinations
- difficulty breathing
- visual disturbances
- muscle spasm or weakness
- convulsions
- slow heartbeat
- nausea, vomiting, diarrhoea

If you forget to take TEVA BACLOFEN 10:

Do not take a double dose to make up for forgotten individual doses.

If you forget to take a dose take it as soon as you remember, and then take the next dose at the right time.

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If you stop taking TEVA BACLOFEN 10:

Do not stop taking TEVA BACLOFEN 10 without telling your doctor. If the doctor decides to stop your treatment with TEVA BACLOFEN 10, the dose will be reduced gradually to prevent withdrawal symptoms. If you stop taking TEVA BACLOFEN 10 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.

4. Possible side effects:

TEVA BACLOFEN 10 can have side effects.

Not all side effects reported for TEVA BACLOFEN 10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TEVA BACLOFEN 10, please consult your healthcare provider for advice.

If any of the following happens, stop taking TEVA BACLOFEN 10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- allergic rash or itching,
- fainting (from low blood pressure)
- convulsions

These are all very serious side effects. If you have them, you may have had a serious reaction to TEVA BACLOFEN 10. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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- breathing difficulties
- excessively weak limbs or feeling tired and exhausted, aching muscles
- unsteadiness, trembling (shaking) or other problems with muscle control
- trouble breathing during sleep (sleep apnoea syndrome)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, dizziness or light-headedness
- feeling depressed, sleeplessness, tiredness, muscle pain
- mood changes, confusion, hallucinations or nightmares
- dry mouth, muscle pain
- a problem with focusing, problems with seeing, rapid involuntary movements of the eyes
- heart problems
- stomach problems including retching, nausea, vomiting, constipation and diarrhoea
- excessive sweating
- increased need to pass urine or pain on passing urine, bed-wetting

Less frequent side effects:

- numbness or tingling in hands or feet
- disturbed sense of taste
- weakness in the muscles used for speech
- mental weariness, feeling overtired
- ringing in the ears
- pain in the stomach

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- liver problems
- difficulty in passing urine
- sexual problems in men, e.g., impotence
- hypothermia (low body temperature)

Frequency unknown:

- slow heartbeat
- hives
- your unborn baby will also be exposed to TEVA BACLOFEN 10 if you took it while pregnant. After birth your baby may develop withdrawal symptoms such as convulsions (symptoms of withdrawal are described in the section “If you stop taking TEVA BACLOFEN 10”).
- increase in blood sugar

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of TEVA BACLOFEN 10.

5. How to store TEVA BACLOFEN 10

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in a dry place and protect from light and moisture.

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Keep blister in carton until required for use.

Do not take the tablets after the expiry date which is printed on the outside of the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information**What TEVA BACLOFEN 10 contains**

The active substance is baclofen.

The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

What TEVA BACLOFEN 10 looks like and contents of the pack

White, round, plain, flat, beveled edged tablets with a breakline on one side and engraved 3K2 on the reverse.

The breakline can be used to divide the tablet into equal halves.

Blister strips of 10 tablets in pack sizes of 30 and 100. Blister strips are packed into an outer cardboard carton.

Tampertainers with 30, 100 and 500 tablets.

Holder of Certificate of Registration

Teva Pharmaceuticals (Pty) Ltd.

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2090

South Africa

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Tel: (011) 055 0200

Registration numbers

30/2.10/0392

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