Applicant: Teva Pharmaceuticals (Pty) Ltd	**Product name:** Baclofen 10 Teva **Dosage form & strength:** Each tablet contains 10 mg baclofen

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

BACLOFEN 10 TEVA, tablets

Baclofen

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

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

- 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.
- BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BACLOFEN 10 TEVA

3. HOW TO TAKE BACLOFEN 10 TEVA

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE BACLOFEN 10 TEVA

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT BACLOFEN 10 TEVA 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 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 BACLOFEN 10 TEVA:

Do not take BACLOFEN 10 TEVA:

- if you are hypersensitive (allergic) to baclofen or any of the other ingredients of BACLOFEN 10 TEVA (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 BACLOFEN 10 TEVA:

Check with your doctor or pharmacist before taking BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA may make some of the symptoms worse or cause new ones
- suffer from epilepsy, as BACLOFEN 10 TEVA 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
- 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 BACLOFEN 10 TEVA 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 10 TEVA:

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 BACLOFEN 10 TEVA with alcohol:

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

BACLOFEN 10 TEVA with food and drink:

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

Pregnancy and breastfeeding and fertility:

BACLOFEN 10 TEVA should not be used during pregnancy.

The safety of using BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA.

Fertility:

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

Driving and using machines:

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

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

It is not always possible to predict to what extent BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA affects them.

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

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

3. HOW TO TAKE BACLOFEN 10 TEVA:

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

Always take BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA is too strong or too weak, talk to your doctor or pharmacist.

The final dose of BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA should be taken.

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

Adults:

The recommended dose is 5 mg BACLOFEN 10 TEVA (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 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 BACLOFEN 10 TEVA will last. If you have the impression that the effect of BACLOFEN 10 TEVA is too strong or too weak, tell your doctor or pharmacist.

If you take more BACLOFEN 10 TEVA than you should:

In the event of overdosage, 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 BACLOFEN 10 TEVA:

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.

If you stop taking BACLOFEN 10 TEVA:

Do not stop taking BACLOFEN 10 TEVA without telling your doctor. If the doctor decides to stop your treatment with BACLOFEN 10 TEVA, the dose will be reduced gradually to prevent withdrawal symptoms. If you stop taking BACLOFEN 10 TEVA suddenly, you may experience unpleasant side effects including anxiety, confusion, hallucinations, convulsions, unusual behaviour, fast heartbeat and temporary worsening of the condition being treated.

4. POSSIBLE SIDE EFFECTS:

BACLOFEN 10 TEVA can have side effects.

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

If any of the following happens, stop taking BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA. 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:

- 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
- 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 BACLOFEN 10 TEVA 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 BACLOFEN 10 TEVA**)

- 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 BACLOFEN 10 TEVA.

5. HOW TO STORE BACLOFEN 10 TEVA:

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.

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 BACLOFEN 10 TEVA contains:

The active substance is baclofen.

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

What BACLOFEN 10 TEVA looks like and contents of the pack:

White, round, plain, flat, bevelled edged tablets with a break line on one side and engraved '3K2' on the reverse. The break line 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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Registration number:

30/2.10/0392

This leaflet was last revised in:

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