SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BACLOFEN 10 BIOTECH: Each tablet contains 10 mg **baclofen**.

BACLOFEN 25 BIOTECH: Each tablet contains 25 mg **baclofen**.

Please read this leaflet carefully before using BACLOFEN 10/25 BIOTECH tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- BACLOFEN 10/25 BIOTECH 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.

1. WHAT BACLOFEN 10/25 BIOTECH CONTAINS

The active substance is baclofen.

Dibasic Calcium Phosphate anhydrous, Colloidal silicon dioxide, Magnesium stearate, Microcrystalline cellulose, and Sodium carboxymethyl starch.

BACLOFEN 10/25 BIOTECH containing 10 mg or 25 mg baclofen contains lactose, 40 mg & 60 mg, respectively per tablet.

2. WHAT BACLOFEN 10/25 BIOTECH IS USED FOR

BACLOFEN 10/25 BIOTECH belongs to a group known as centrally acting muscle relaxants.

BACLOFEN 10/25 BIOTECH is used in adults to treat spasticity of the skeletal muscle due to multiple sclerosis, or spastic conditions occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic or unknown etiology.

3. BEFORE YOU USE BACLOFEN 10/25 BIOTECH

Do not use BACLOFEN 10/25 BIOTECH:

- If you are hypersensitive (allergic) to Baclofen or any of the inactive ingredients of BACLOFEN 10/25 BIOTECH**.**
- If you have a galactose – lactose allergy or intolerance.
- If you suffer from epilepsy or seizures.
- If you have an active gastric or duodenal (stomach or small bowel) ulcer.
- If you have porphyria.
- If you are pregnant or are breastfeeding your baby.

Take special care with BACLOFEN 10/25 BIOTECH:

Special care should be taken in the following cases and you should inform your doctor if you suffer from any of the following:

- Hypertension and are currently on high blood pressure medication, as it can lower your blood pressure drastically.
- The use of BACLOFEN 10/25 BIOTECH may lead to drowsiness, visual disturbances and impaired concentration which may be aggravated by the simultaneous intake of alcohol or central nervous system depressants agents.
- If you ever had a stroke, you may not tolerate this treatment well.

- If you have been diagnosed with Parkinson's disease and are on levodopa (alone or in combination with carbidopa) treatment. Your Parkinson's symptoms may get worse if you start taking BACLOFEN 10/25 BIOTECH.
- If you suffer from psychiatric disorders, schizophrenia and depressive, manic disorders or confusional states, and treated with BACLOFEN 10/25 BIOTECH, your symptoms may also get worse and you should be monitored while receiving treatment.
- If you are taking lithium for your depression.
- If you have an active peptic ulcer or have a history of peptic ulcer.
- If you suffer from cerebrovascular disease.
- If you have diabetes (high blood sugar), as it can cause an increase in blood sugar.
- If your kidneys, bladder or liver are not functioning properly.
- BACLOFEN 10/25 BIOTECH should be used with caution in patients in whom spasticity is used to maintain posture or increase functional capacity.

Whilst you are taking BACLOFEN 10/25 BIOTECH, your doctor may want to give you a check-up from time to time.

Taking BACLOFEN 10/25 BIOTECH with food and drink

You are advised NOT to drink alcohol with BACLOFEN 10/25 BIOTECH. Discuss with your doctor if you have any questions.

Swallow these tablets with water.

BACLOFEN 10/25 BIOTECH should be taken for as long as your doctor tells you to, it may be dangerous to stop treatment without their advice.

Pregnancy and breastfeeding:

The sage use of BACLOFEN 10/25 BIOTECH during pregnancy and breastfeeding has not been established.

You should not use BACLOFEN 10/25 BIOTECH if you are pregnant or breastfeeding your baby.

Please consult your health care provider for advice.

Baclofen crosses the placenta and is distributed into breast milk.

Driving and using machinery:

BACLOFEN 10/25 BIOTECH can cause sleepiness, dizziness and low blood pressure. Do not drive a motor vehicle or operate machinery until you know how BACLOFEN 10/25 BIOTECH affects you.

Important information about soe of the ingredients of BACLOFEN 10/25 BIOTECH

BACLOFEN 10/25 BIOTECH contains lactose (milk sugar) and should not be administered to patients with rare hereditary problems. or a history of lactose intolerance. Lapp lactose deficiency or glucose-galactose malabsorption.

Taking other medicines with BACLOFEN 10/25 BIOTECH

Always tell your health care provided if you are taking any other medicine. (This includes complimentary or traditional medicines).

BACLOFEN 10/25 BIOTECH can cause interactions with the following medicines:

- Alcohol and other central nervous system (CNS) depressants, or sleeping tablets, as they may worsen the CNS effects of BACLOFEN 10/25 BIOTECH, especially sedation (making you feel sleepy) and should be avoided.
- Lithium (for bipolar disease or depression) as an increase in intensity of uncontrolled muscle action can occur, and should be avoided taking together.

- Tricyclic antidepressants (e.g. amitriptyline or imipramine), as you may experience an increase in muscle weakness.
- Medicines to treat high blood pressure (e.g. propranolol, nifedipine, captopril), as you may experience extreme lowering pf blood pressure.
- NSAID's (anti-inflammatory pain medicine for example ibuprofen), as they may reduce BACLOFEN 10/25 BIOTECH excretion.
- if you are treatment for Parkinson's disease, as this combination can lead to mental confusion, hallucinations, headaches, nausea and agitation.

Please consult your health care provider for advice.

4. HOW TO USE BACLOFEN 10/25 BIOTEC

Always take BACLOFEN 10/25 BIOTECH exactly as your doctor has instructed you. Do not take more or less tablets and do not take them more often than recommended. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of BACLOFEN 10/25 BIOTECH is too strong or too weak, talk to your health care provider.

Adults:

Treatment should as a rule be started with a dosage of 5 mg three times daily. BACLOFEN 10/25 BIOTECH should be taken during meals with a little liquid.

The usual BACLOFEN 10/25 BIOTECH dosage is 5 mg three times daily, gradually increasing up to 20 mg three times daily.

Your doctor might decide to increase your dosage depending on your specific need.

Patients with kidney problems:

Your health care provided may give you a lower dose (e.g. 5 mg daily).

Elderly patients:

Elderly patients are more likely to experience side effects; caution is advised and your health care provider will monitor your treatment carefully.

Children:

This presentation/dosage form is not recommended for children.

Do not stop taking the tablets suddenly as your symptoms may get worse or you may suffer confusion, hallucinations, changes in your mental state, fits or a fast heartbeat. Treatment with BACLOFEN 10/25 BIOTECH is usually reduced slowly and gradually over a period of 1-2 weeks.

If you take more BACLOFEN 10/25 BIOTECH than you should:

In the event of overdosage you can experience seizures or coma. Consult your health care provider. If neither is available, seek help at the nearest hospital or poison control centre. There is no specific antidote.

Take the empty container and any remaining tablets along with the patient so that the doctor can see what the patient have taken.

If you forget to take BACLOFEN 10/25 BIOTECH:

If you forget to take a dose, take it as soon as you remember.

Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

Effects when treatment with BACLOFEN 10/25 BIOTECH is stopped:

Sudden withdrawal of BACLOFEN 10/25 BIOTECH after long term administration may cause continuous muscle tension and spasticity, severe high fever, altered mental status (feeling confused), and has progressed in rare instance to skeletal muscle tissue breakdown, multiple organ-system failure and death. Other withdrawal symptoms are hallucinations, anxiety and a heart rate that exceeds the normal range.

5. POSSIBLE SIDE EFFECTS

BACLOFEN 10/25 BIOTECH can have side effects. Not all side effects reported for BACLOFEN 10/25 BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BACLOFEN 10/25 BIOTECH, please consult your health care provided for advice.

If any of the following happens, stop taking BACLOFEN 10/25 BIOTECH 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',
- rash or itching
- fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to BACLOFEN 10/23 BIOTECH. 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:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,

- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

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:

- drowsiness
- nausea
- sleepiness during the day
- tiredness or weakness
- insomnia
- light-headedness
- dizziness
- confusion
- headache
- nightmares
- difficulty breathing
- sight disturbances
- constipation or diarrhoea

- dry mouth
- Rash or itchy skin

Less frequent side effects:

- irregular and jerky movements
- increase in spastic symptoms
- shakiness in the arms and legs
- fits
- Euphoria (feeling very happy)
- uncontrolled eye movements
- difficulty in focusing
- hallucinations
- stomach pain
- itching
- impotence
- swelling of the ankles
- In-coordination
- depression
- stiff muscles
- ringing in the ears
- chest pain

- fast irregular heartbeat
- blood in the urine
- Erectile dysfunction
- Helplessness

The following side effects have been reported but the frequency is not known:

- forgetfulness
- increased sweating
- difficulty to urinate
- weight gain or weight loss
- increased urination during night time

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

6. STORING AND DISPOSING OF BACLOFEN 10/25 BIOTECH

Store at or below 25 °C and protect from moisture.

Do not store your tablets in the bathroom.

Keep the tablets in the original container until required for use.

Keep the container well closed.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton or blister.

Return all unused medicine to your pharmacist

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

7. PRESENTATION OF BACLOFEN 10/25 BIOTECH

BACLOFEN 10/25 BIOTECH:

Securitainers, HDPE and amber glass containers containing 30 and 100 tablets.

Silver aluminium, clear transparent PVC/PVdC blister packs. Each strip containing ten tablets with 3 blister strips per outer carton.

Polyethylene zip-lock pouches containing 28 tablets.

8. IDENTIFICATION OF BACLOFEN 10/25 BIOTECH

10 mg: 7.5 mm round, biconvex, white tablet with score mark on one side.

25 mg: 8 mm Flat bevelled edge white tablet with score mark on one side and plain on other side.

9. REGISTRATION NUMBER

BACLOFEN 10 BIOTECH - W/2.10/0236

BACLOFEN 25 BIOTECH – W/2.10/0237

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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