

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S3**TORASEMIDE BIOTECH 5 tablets****TORASEMIDE BIOTECH 10 tablets****TORASEMIDE BIOTECH 20 tablets****Torasemide****Contains sugar (lactose monohydrate):**

TORASEMIDE BIOTECH 5 contains 79 mg, TORASEMIDE BIOTECH 10 contains 158 mg,
TORASEMIDE BIOTECH 20 contains 316 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking TORASEMIDE BIOTECH tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TORASEMIDE 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.

What is in this leaflet

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

1. What TORASEMIDE BIOTECH is and what it is used for

TORASEMIDE BIOTECH contains a medicine called torasemide. This belongs to a group of medicines called 'diuretics' or 'water tablets'. TORASEMIDE BIOTECH is used to:

- Treat high blood pressure (hypertension).
- Treat swelling caused by too much water in the body (oedema).

The tablets work by making you pass more water (urine).

2. What you need to know before you take TORASEMIDE BIOTECH

Do not take TORASEMIDE BIOTECH:

- If you are hypersensitive (allergic) to torasemide or any of the other ingredients of TORASEMIDE BIOTECH (listed in section 6).
- If you are hypersensitive (allergic) to medicines called 'sulphonylureas'. These are used to treat diabetes (high blood sugar). These medicines include chlorpropamide, glibenclamide, glipizide and tolbutamide.
- If you have kidney problems (renal failure) with absence of urine production (anuria).
- If you have liver problems.
- If you have kidney problems (renal failure) with absence of urine production (anuria).
- If you have liver problems.
- If you are pregnant or breastfeeding your baby. See section 'Pregnancy and breastfeeding'.
- If you have a low volume of blood (hypovolaemia).
- If you have low levels of sodium or potassium in your blood (hyponatraemia or hypokalaemia).
- If you have severe disorders of passing water (urinating).
- If you are aged 12 years or younger.

Warnings and precautions

Take special care with TORASEMIDE BIOTECH:

- If you have low levels of potassium or sodium in your blood (shown in blood tests).

- If you have an enlarged prostate or have difficulty passing water (urinating).
- If you have gout or high levels of uric acid in your blood.
- If you have diabetes (diabetes mellitus).
- If you have low blood pressure (hypotension).
- If you have heartbeat problems (cardiac dysrhythmia).

If any of these apply to you, or if you are not sure, talk to your doctor or pharmacist before you take TORASEMIDE BIOTECH.

Children and adolescents

TORASEMIDE BIOTECH is not for use in children and adolescents below 12 years of age.

Other medicines and TORASEMIDE BIOTECH

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

Tell your doctor if you are taking any of the following medicines:

- Medicine for high blood pressure called ACE (angiotensin-converting enzyme) inhibitor inhibitors (for e.g. enalapril).
- Insulin or other medicine used to treat diabetes.
- Aminoglycoside or cephalosporin antibiotics such as streptomycin, gentamycin, cephalexin and ceftriaxone.
- Amphotericin B (antifungal medicine).
- Anti-inflammatory medicines such as indomethacin or ibuprofen.
- A medicine used for heart failure or irregular heartbeat such as digoxin.
- Lithium (medicine to stabilise your mood).
- Medicines containing salicylates such as aspirin or salazopyrin.
- Theophylline (a medicine used to treat asthma).

- Steroid medicines, such as hydrocortisone, prednisolone and dexamethasone.
- Laxatives.
- Adrenaline (also called epinephrine) or noradrenaline (also called norepinephrine). These are used to treat low blood pressure.
- Colestyramine, or other 'ion exchange resins' (used to treat high levels of cholesterol in your blood).
- Medicines to relax your muscles (muscle relaxants).
- Cisplatin (used to treat cancer).
- Probenecid (used to treat gout).

Dosage adjustment may be required when using blood thinning tablets like warfarin in combination with TORASEMIDE BIOTECH.

TORASEMIDE BIOTECH with food and drink

TORASEMIDE BIOTECH can be taken with or without food.

Pregnancy, breastfeeding and fertility

TORASEMIDE BIOTECH should not be used by pregnant or breastfeeding women.

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 TORASEMIDE BIOTECH.

Driving and using machines

TORASEMIDE BIOTECH may affect your ability to drive a motor vehicle or operate machinery. If you are feeling nauseous, dizzy or weak do not drive a vehicle or operate machinery.

TORASEMIDE BIOTECH contains lactose monohydrate

TORASEMIDE BIOTECH contains lactose monohydrate which is a type of sugar. If you have been

told by your doctor that you have an intolerance to some sugars contact your doctor before taking TORASEMIDE BIOTECH.

3. How to take TORASEMIDE BIOTECH

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

Always take TORASEMIDE BIOTECH exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

High blood pressure

The usual dose for adults and elderly people is between 2,5 mg and 5 mg TORASEMIDE BIOTECH once a day.

Water retention (oedema)

The treatment starts with 5 mg TORASEMIDE BIOTECH once a day. Your doctor or healthcare provider may increase the dosage up to 40 mg TORASEMIDE BIOTECH per day.

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

If you take more TORASEMIDE BIOTECH than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre as soon as possible. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take TORASEMIDE 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.

4. Possible side effects

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

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

- Swelling of the hands, feet, ankles, face, lips, 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 TORASEMIDE 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:

- Bleeding or bruising more easily than normal.
- Frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- Tiredness, being short of breath and looking pale.
- Blockage of a blood vessel by a blood clot elsewhere in the body.
- Chest pain.
- Increase in heart rate.
- Dizziness and light-headedness.
- Yellowing of the eyes or skin, stomach pain, dark coloured urine.
- Widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30 % of the body surface – toxic epidermal

necrosis).

- Difficulty in passing urine, increased urge to urinate or more-frequent urination.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Lack of energy, drowsiness, weakness, muscle cramps, restlessness, dehydration, dry mouth and thirst – these may be signs of a disturbance in the balance of electrolytes (salts) in your blood.
- Headache, dizziness.
- Loss of appetite, upper stomach pain, nausea (feeling sick), vomiting (being sick), diarrhoea, constipation.
- Muscle spasms.
- Fatigue, unusual tiredness or weakness.

Less frequent side effects:

- Skin sensitive to the sun.
- Buzzing or ringing in ears, loss of hearing.
- Low levels of potassium in your blood. This may cause, feeling weak, feeling sleepy, feeling confused or cramps.
- High uric acid levels in your blood.
- Increased blood sugar levels.
- Increased levels of cholesterol and triglycerides (fats) in your blood.

Frequency unknown side effects

- Blurred or disturbed vision.
- Confusion.
- Tingling or numbness of the hands or feet.
- Spinning sensation, difficulty speaking, slurred speech, loss of co-ordination.

- Inflammation of the pancreas, with severe upper stomach pain often with nausea (feeling sick) and vomiting (being sick).

If you notice any other 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 or pharmacist. 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 TORASEMIDE BIOTECH.

5. How to store TORASEMIDE BIOTECH

- Store at or below 25 °C.
- Keep tablets in the outer carton until required for use.
- Keep container well closed.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the container or blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TORASEMIDE BIOTECH contains

The active substance is torasemide.

TORASEMIDE BIOTECH 5: Each tablet contains 5 mg torasemide.

TORASEMIDE BIOTECH 10: Each tablet contains 10 mg torasemide.

TORASEMIDE BIOTECH 20: Each tablet contains 20 mg torasemide.

The inactive ingredients are crospovidone, lactose monohydrate, magnesium stearate,

microcrystalline cellulose and povidone

What TORASEMIDE BIOTECH looks like and contents of the pack

TORASEMIDE BIOTECH 5: White to off white, oval shaped, scored tablets, debossed with '5' on plain side and scored on the other side.

TORASEMIDE BIOTECH 10: White to off white, oval shaped, scored tablets, debossed with '10' on plain side and scored on the other side.

TORASEMIDE BIOTECH 20: White to off white, oval shaped, scored tablets, debossed with '20' on plain side and scored on the other side.

TORASEMIDE BIOTECH 5 & 10:

30 and 100 tablets are packed in white HDPE container with white ribbed child resistant HDPE cap with a pulp liner in between the heat seal liner and inner cap, placed in outer cardboard carton.

TORASEMIDE BIOTECH 20:

100 tablets are packed in white HDPE container with white ribbed child resistant HDPE cap with a pulp liner in between the heat seal liner and inner cap, placed in outer cardboard carton.

All pack size and strengths may not necessarily be marketed at one time.

Holder of certificate of registration

Biotech Laboratories (Pty) Ltd

Ground Floor, Block K West, Central Park

400 16th Road, Randjespark

Halfway House

Midrand 1685

011 848 3050

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