

### 1.5.5 Clean Proposed Patient Information Leaflet

**SCHEDULING STATUS:**

S3

#### **FUROBE 40 mg TABLET**

Furosemide

Sugar free

**Read all of this leaflet carefully before you start taking FUROBE 40 mg TABLET.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FUROBE 40 mg TABLET 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 FUROBE 40 mg TABLET is and what it is used for
2. What you need to know before you take FUROBE 40 mg TABLET
3. How to take FUROBE 40 mg TABLET
4. Possible side effects
5. How to store FUROBE 40 mg TABLET
6. Contents of the pack and other information

## **1. WHAT FUROBE 40 mg TABLET IS USED FOR**

FUROBE 40 mg TABLET belongs to a group of medicines called diuretics (water tablets).

FUROBE 40 mg TABLET is used to get rid of excess fluid from the body, and in the treatment of high blood pressure. Excess fluid can build up in certain conditions which affect the heart, lungs, kidneys or liver.

FUROBE 40 mg TABLET is used to remove that fluid by making you pass more water.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FUROBE 40 mg TABLET**

### **Do not take FUROBE 40 mg TABLET:**

- if you are hypersensitive (allergic) to furosemide, sulphur or any of the other ingredients of FUROBE 40 mg TABLET
- if you have kidney disease
- if you have severe liver problem
- if you are pregnant or breast-feeding your baby.

### **Warnings and precautions**

#### **Take special care with FUROBE 40 mg TABLET**

- if you have gout
- if you have difficulty in passing urine
- if you have diabetes
- if you are suffering from dehydration.
- when taking cephalosporin antibiotics together with FUROBE 40 mg TABLET, as nephrotoxicity (damage to your kidneys) may occur.
- if you have elevated cholesterol levels.
- if you have muscle cramps, you may need a potassium rich diet or potassium sparing medication.

- if you have muscle cramps/spasms which can be increased due to reduction in calcium levels

### **Other medicines and FUROBE 40 mg TABLET**

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

Take care if you are using any of the following medicines with FUROBE 40 mg TABLET

- Medicines used for heart problems (such as digoxin)
- Antibiotics for infections (e.g. kanamycin, gentamicin, tobramycin), may affect your hearing and FUROBE 40 mg TABLET may make this worse if taken together.
- FUROBE 40 mg TABLET may diminish the potency of medicines that control diabetes
- Medicines for depression (such as lithium); medicines for asthma (such as theophylline, some muscle relaxants and aspirin related medicines. FUROBE 40 mg TABLET may potentiate their effect.
- Medicines to lower blood pressure (such as ACE-inhibitors or beta-blockers. FUROBE 40 mg TABLET may potentiate their effect
- Medicines used to reduce inflammation (NSAIDs) such as indomethacin, acetylsalicylic acid may antagonise the action of FUROBE 40 mg TABLET and may cause renal failure in case of pre-existing decreased volume of circulating blood in the body.
- Concurrent use of FUROBE 40 mg TABLET and sucralfate (used for ulcers) should be avoided as sucralfate reduces the absorption of furosemide and hence weakens its effect.

### **Pregnancy, breast-feeding and fertility**

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 being taking this medicine.

Do not take FUROBE 40 mg TABLET if you are pregnant.

FUROBE 40 mg TABLET should not be taken by breast feeding women.

### **Driving and using machines**

Do not drive or operate machinery if you feel drowsy or have blurred vision after taking FUROBE 40 mg TABLET.

### **3. HOW TO TAKE FUROBE 40 mg TABLET**

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

Always take FUROBE 40 mg TABLET exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

The usual starting dose for excess fluid is 40 mg in the morning, but this may be reduced to 20 mg daily for maintenance. Your doctor may decide to increase your dose further if necessary. For doses exceeding 120 mg per day, it should be taken as 2 or 3 separate doses during the day.

The usual dose for the treatment of high blood pressure is 40 mg to 80 mg daily. Your doctor may prescribe another medicine for high blood pressure, to be taken together with FUROBE 40 mg TABLET.

Children's dosages are usually in 1 to 3 mg per kg body weight. A maximum dose of 120 mg should not be exceeded.

**Taking FUROBE 40 mg TABLET with food and drink:**

FUROBE 40 mg TABLET should be taken in the morning with or without food.

Your doctor will tell you how long your treatment with Furobe 40 mg TABLET will last. If you have the impression that the effect of FUROBE 40 mg TABLET is too strong or too weak, talk to your doctor or pharmacist.

**If you take more FUROBE 40 mg TABLET than you should**

If you take an overdose, fluid, electrolyte depletion and dehydration are the most common symptoms. The treatment for overdose is water and electrolyte replacement in accordance with urine output. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

**If you forget to take FUROBE 40 mg TABLET**

If you forget to take a dose, take another as soon as you remember. Then take your next dose at the normal time.

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

**4. POSSIBLE SIDE EFFECTS:**

FUROBE 40 mg TABLET can have side effects.

Not all side effects reported for FUROBE 40 mg TABLET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FUROBE 40 mg TABLET, please consult your health care provider for advice.

If any of the following happen, you should stop taking FUROBE 40 mg TABLET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you experience a severe allergic reaction (which may include symptoms such as skin rashes, inflammation of blood vessels (which cause fever, weight loss and muscle and joint pain), allergic to light, high fever, red patches on the skin)
- sudden inflammation of the pancreas accompanied by severe pain in the upper abdomen, shifting towards the back.

These are very serious side effects. If you have them you may have had a serious allergic reaction or other type of reaction to FUROBE 40 mg TABLET. 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:

- decrease in white blood cells. Signs include: fever, chills, sore throat,
- low number of cells involved with blood clotting. Signs include: more or worse bruises than normal, small purple or red dots under your skin, nosebleeds or bleeding gums, black or bloody-looking bowel movements, red or pink urine,
- a high level of disease-fighting white blood cells known as eosinophils in the blood,
- decreased number of red blood cells. Signs include: tiredness, pale colour weakness,
- reduced blood calcium and potassium levels. Signs include: muscle cramps,
- high levels of blood sugar leading to altered levels of consciousness,
- difficulty breathing
- blurred vision,
- changes in the way your heart beats (if you notice it beating faster)
- reduced hearing and any ringing sensation in the ears
- constant tingling in your limbs which could be a sign of poor blood circulation in the body
- less urine than is normal for you
- tiredness, forgetfulness, slurred speech and disorientation caused by liver dysfunction which did not remove toxins from the blood

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:

- light headed sensation when standing up

Less frequent side effects:

- nausea, vomiting and diarrhea
- dry mouth and thirst
- constipation
- inflammation of the skin
- gout causing severe pain and redness in joints, especially the big toe,
- fatigue

Frequency unknown side effects:

- dehydration caused by a lack of water in the body
- increased cholesterol (fat) in the blood,
- dizziness,
- fainting

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 or 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 FUROBE 40 mg TABLETS.

## 5. HOW TO STORE FUROBE 40 mg TABLET

Store in a cool place at or below 25 °C. Protect from light.

Store all medicines out of reach of children

Do not store in bathrooms in order to protect from light.

Do not take the medicine after the expiry date stated on the Label.

Return all unused medicine to your pharmacist.

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

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### WHAT FUROBE 40 mg TABLET CONTAINS

#### FUROBE 40 mg TABLET

The active substance is furosemide 40 mg per tablet

Each **FUROBE 40 mg TABLET** contains furosemide 40 mg

The other ingredients are:

Ac-Di-Sol, magnesium stearate, microcrystalline cellulose, purified talc, purified water, sodium bicarbonate, starch maize.

### What FUROBE 40 mg TABLET looks like and the contents of the pack

#### FUROBE 40 mg TABLET

White to off-white tablet, scored on the one side.

Containers of 30, 84, 250 and 5000 tablets. Patient ready packs of different pack sizes

### Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road,

Stormill, Ext. 1,

Roodepoort,

**Applicant/PHCR:** Ranbaxy Pharmaceuticals (Pty) Ltd  
**Product proprietary name:** FUROBE 40 mg TABLET

**Dosage form and strength:** Tablets / 40 mg  
**Date of Amendment:** May 2021

1724

**This leaflet was last revised in**

To be allocated

**Registration Number**

FUROBE 40mg TABLET - S/18.1/31

Namibia 30's, 250's:	NS2	90/18.1/00371
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