

# FUROSEMIDE 40 BIOTECH

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

**[S3]**

Furosemide 40 Biotech, capsule
Furosemide
Contains sugar (lactose 90,0 mg per capsule)

#### Read all of this leaflet carefully before you start taking Furosemide 40 Biotech

- 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.
- Furosemide 40 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

- What Furosemide 40 Biotech is and what it is used for
- What you need to know before you take Furosemide 40 Biotech
- How to take Furosemide 40 Biotech
- Possible side effects
- How to store Furosemide 40 Biotech
- Contents of the pack and other information

#### 1. What Furosemide 40 Biotech is and what it is used for

Furosemide tablets is one of a group of medicines called diuretics (water tablets). Your doctor has prescribed Furosemide 40 Biotech tablets to treat a condition called oedema where there is too much water in your body. This could be due to problems with your heart, lungs, kidneys, liver, blood vessels or high blood pressure. Furosemide 40 Biotech helps your kidneys to get rid of the extra water that is not needed in your body.

#### 2. What you need to know before you take Furosemide 40 Biotech

##### Do not take Furosemide 40 Biotech if:

- you are allergic (hypersensitive) to furosemide, sulphonamides or any of the other ingredients in Furosemide 40 Biotech tablets (see section 6)
- you have elevated levels of urea and other nitrogen compounds in your blood
- you have a condition which is characterised by low blood volume (with or without low blood pressure)
- you have low levels of salts (potassium and sodium) in your blood
- you are dehydrated
- your urine output is below normal
- you have severe kidney damage which has stopped them working properly and producing urine
- you have liver cirrhosis (tiredness, weakness, water retention, feeling or being sick, loss of weight or appetite, yellowing skin or eyes, itch) or liver encephalopathy (confusion, altered levels of consciousness and coma as a result of liver failure)
- you are breastfeeding your baby.

#### Warnings and precautions

##### Take special care with Furosemide 40 Biotech if:

- you have low blood volume (hypovolaemia) or are at risk of developing low blood pressure
- you have low levels of protein in your blood (hypoproteinaemia) as a result of kidney damage
- you have liver congestion (slowed blood flow through the vessels) or other liver problems
- you have kidney problems
- you may have diabetes. If you are taking insulin, your doctor may need to adjust your insulin dosage
- you are elderly, if you are on other medications which can cause the drop of blood pressure and if you have other medical conditions that are risks for the drop of blood pressure
- you have prostate trouble or difficulty passing urine
- you have had gout
- you have an abnormal blood condition
- you are to undergo any blood or urine tests.

#### Other medicines and Furosemide 40 Biotech

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

- medicines to lower blood pressure, such as ACE inhibitors, renin inhibitors, alpha blockers, calcium channel blockers, diuretics, phenothiazines
- medicines to treat mental illness (e.g., pimozide, amisulpride, sertindole)
- medicines for dysrhythmias (e.g., sotalol, amiodarone, flecainide)
- digoxin for your heart
- moxisylyte for Raynaud's syndrome
- nitrates (for angina)
- lithium for depression or mania
- sucralfate for stomach ulcers
- cholestryramine or colestipol for high cholesterol
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g., ibuprofen or naproxen
- aspirin for pain
- antibiotics for infections that affect your kidneys or ears (e.g., cefaclor, colistin, gentamicin, vancomycin)
- antidepressants (e.g., monoamine oxidase inhibitors (MAOIs))
- medicines to control diabetes such as insulin or tablets
- antiepileptics e.g., phenytoin or carbamazepine
- amphotericin (to treat fungal infections)
- corticosteroids or antihistamines (to treat allergic reactions)
- chloral hydrate (to treat insomnia)
- medicines for ADHD
- drugs treating cancer e.g., aldesleukin
- levodopa (for Parkinson's disease)
- oral contraceptives
- alprostadil for erectile dysfunction
- certain treatments for asthma such as theophylline or salbutamol
- probenecid to prevent gout
- if you are about to undergo a procedure where curariform muscle relaxants (e.g., vecuronium) or anaesthetics may be used, tell your anaesthetist/ dentist or healthcare professional
- laxatives used over a long period of time
- medicines or foods containing liquorice

#### Furosemide 40 Biotech with food and drink

Furosemide 40 Biotech may cause an enhanced hypotensive effect.

#### Pregnancy, breastfeeding 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 taking this medicine.

Do not use Furosemide 40 Biotech if you are breastfeeding your baby.

#### Driving and using machines

You may experience reduced mental alertness.

It is not always possible to predict to what extent Furosemide 40 Biotech may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until you are aware of the measure to which Furosemide 40 Biotech affects you.

#### Furosemide 40 Biotech contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this Furosemide 40 Biotech.

#### 3. How to take Furosemide 40 Biotech

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

Always take Furosemide 40 Biotech exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

<p>The usual starting dose is 40 mg in the morning.</p>
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*High blood pressure:* 20–40 mg twice a day.

Children generally receive daily oral doses of 1 mg/kg body weight. If necessary, this dose may be increased step by step to a maximum of 3 mg/kg body weight per day. A dose of 120 mg per day should not be exceeded with children.

Your doctor will tell you how long your treatment with Furosemide 40 Biotech will last. If you have the impression that the effect of Furosemide 40 Biotech is too strong or too weak, tell your doctor or pharmacist.

#### If you take more Furosemide 40 Biotech than you should

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

#### If you forget to take Furosemide 40 Biotech

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

#### 4. Possible side effects

Furosemide 40 Biotech can have side effects.

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

**If any of the following happens, stop taking Furosemide 40 Biotech and tell your doctor immediately or go to the casualty department of 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 Furosemide 40 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:**

- blood disorders, such as bone marrow depression
- cardiac dysrhythmia, a sudden drop in blood pressure when you stand from a seated or prone (lying down) position
- patent ductus arteriosus (PDA) is a persistent opening between the two major blood vessels leading from the heart of a baby

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

#### Tel your doctor if you notice any of the following:

*Frequent side effects:*

- dehydration, altered balance of fluid or chemicals in the body (e.g. sodium, potassium, chlorine, calcium and magnesium) causing a dry mouth, weakness, tiredness or drowsiness, restlessness, fits, muscle pain, fatigue or cramps, low blood pressure causing loss of concentration and slowed reactions, difficulty passing water, fast or irregular heart rate and feeling and being sick
- a condition that occurs when the level of sodium in the blood is too low
- low blood volume
- increased creatinine and blood urea (seen in blood tests)
- results from either low chloride intake or excessive chloride wasting
- too low calcium levels in the blood, too low magnesium in blood
- abnormally low level of the chloride ion in the blood
- light-headedness, sensations of pressure in the head, headache, drowsiness, weakness, changes in vision, dry mouth, dizziness when standing.
- a kidney disorder in which an excess of calcium deposited in the kidneys
- creatinine increased
- blood urea increased

*Less frequent side effects:*

- blood disorders e.g. leukopenia, agranulocytosis, thrombocytopenia
- anaemia causing tiredness, breathlessness, unusual bleeding or bruising
- gout
- changes in the body seen in tests such as levels of cholesterol, glucose uric acid
- changes in blood cells such as amount of white blood cells, reduction of platelets causing a rash fever, sweating, tiredness, and weight loss. Your doctor will perform regular blood tests to ensure no changes have occurred
- dry mouth, thirst, feeling or being sick, changes in bowel movements including diarrhoea and constipation
- psychiatric disorder NOC causing delusions, hallucinations, disorganised speech
- feeling ‘pins and needles’ or tingling sensation
- confusion, headache, tiredness
- changes in vision including blurred or yellow vision
- deafness (sometimes irreversible)
- ‘ringing’ in the ears, loss of hearing usually reversible
- symptoms of shock such as changes in heart rate, breathlessness, cool clammy skin
- dry mouth, thirst, nausea, bowel motility disturbances, vomiting, diarrhoea and constipation

- inflammation of the pancreas causing pains in your abdomen or back and nausea
- changes in the liver causing yellowing of the skin or whites of the eyes
- skin rashes
- photosensitivity, toxic epidermal necrolysis (TEN) is a rare and serious skin condition
- muscle cramps, weakness
- inflammation or failure of the kidney which may cause back pain or changes in the amount or need to urinate
- worsening of conditions where there is already balances of fluid or chemicals in the body
- swelling in between the kidney tubules
- a condition in which the kidneys suddenly can’t filter waste from the blood
- generally feeling tired, unwell, fever

*The frequency of the following side effects is unknown:*

- alkalosis involves a primary increase in serum bicarbonate (HCO3-) concentration,
- excretion of potassium
- dizziness, fainting and loss of consciousness
- acute generalised exanthematous pustulosis (AGEP) (acute febrile drug eruption)
- hives, various forms of dermatitis, allergic skin reactions
- a skin disorder characterised by bull’s-eye-shaped lesions.
- a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters

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 Furosemide 40 Biotech.

#### 5. How to store Furosemide 40 Biotech

Store out of reach of children

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

Do not use after the expiry date stated on the label / carton / bottle

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 Furosemide 40 Biotech contains

Each capsule contains 40 mg of the active substance furosemide.

The other ingredients are colloidal silicon dioxide (Aerosil 200), purified talc and lactose.

The other ingredients are Elanco Opaque Blue 50, Brilliant Blue CI 42090 Erythrosine CI 45430, Elanco Opaque White, Gelatin, Titanium Dioxide CI 77891.

#### What Furosemide 40 Biotech looks like and contents of the pack

Opaque white body/opaque turquoise blue cap, size ‘2’ snap-fit capsule containing white, lump-free powder.

Furosemide 40 Biotech capsules are available in transparent PVC/PVDC/ Aluminium blister packs of 30 tablets. Each blister strip contains 10 capsules and 3 blister strips are packed in an outer carton.

Furosemide 40 Biotech are packed as 30, 112, 250, 1000 and 5000 capsules in white HDPE container.

Patient ready packs (PRP’s) are available in pack sizes of 56 or 84 capsules.

All pack sizes may not necessarily be marketed at one time.

#### Holder of Certificate of Registration

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# FUROSEMIDE 40 BIOTECH

## PASIËNTINLIGTINGSBLAD

### SKEDULERINGSTATUS:

[53]

Furosemide 40 Biotech, kapsule
Furosemied
Bevat suiker (laktose 90,0 mg per kapsule)

### Lees die hele pamflet noukeurig deur voordat jy Furosemide 40 Biotech begin neem

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- As jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- Furosemide 40 Biotech is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

### Wat is in hierdie pamflet

- Wat Furosemide 40 Biotech is en waarvoor dit gebruik word
- Wat jy moet weet voordat jy Furosemide 40 Biotech neem
- Hoe om Furosemide 40 Biotech te neem
- Moontlike nuwe-effekte
- Hoe om Furosemide 40 Biotech te bewaar
- Inhoud van die pakkie en ander inligting

### 1. Wat Furosemide 40 Biotech is en waarvoor dit gebruik word

Furosemied-tablette is een van ’n groep medisyne wat diuretika (watertablette) genoem word.

Jou dokter het Furosemide 40 Biotech-tablette vir jou voorgeskryf om ’n toestand genaamd edeem te behandel waar daar te veel water in jou liggaam is. Dit kan wees as gevolg van probleme met jou hart, longe, niere, lewer, bloedvate of hoë bloeddruk. Furosemide 40 Biotech help jou niere om ontslae te raak van die ekstra water wat nie in jou liggaam nodig is nie.

### 2. Wat jy moet weet voordat jy Furosemid 40 Biotech neem

#### Moenie Furosemide 40 Biotech neem as:

- jy allergies (hipersensitief) is vir furosemied, sulfonamiede of enige van die ander bestanddele in Furosemide 40 Biotech tablette (sien afdeling 6)
- jy verhoogde vlakke van ureum en ander stikstofverbindings in jou bloed het
- jy ’n toestand het wat gekenmerk word deur lae bloedvolume (met of sonder lae bloeddruk)
- jy lae vlakke van soute (kalium en natrium) in jou bloed het
- jy gedehidreer is
- jou uriene-uitset onder normaal is
- jy ernstige nierskade het wat veroorsaak het dat hulle nie behoorlik werk en uriene produseer nie
- jy lewersirrose (moegheid, swakheid, waterretensie, voel of jy siek is, verlies van gewig of eetlus, vergelende vel of oë, jeuk) of lewerenkefalopatie (verwarring, veranderde vlakke van bewussyn en koma as gevolg van lewerversaking)
- jy jou baba borsvoed.

#### Waarskuwings en voorsorgmaatreëls

#### Wees veral versigtig met Furosemide 40 Biotech indien:

- jy ’n lae bloedvolume (hipovolemie) het of die risiko loop om lae bloeddruk te ontwikkel
- jy lae vlakke van proteïene in jou bloed het (hipoproteïenemie) as gevolg van nierskade
- jy lewer opeenhoping (vertraagde bloedvloei deur die vate) of ander lewerprobleme het
- jy nierprobleme het
- jy diabetes kan hê. As jy insulien neem, sal jou dokter dalk jou insuliendosis moet aanpas
- jy bejaard is, as jy ander medikasie gebruik wat die daling van bloeddruk kan veroorsaak en as jy ander mediese toestande het wat risiko’s vir die daling van bloeddruk inhou
- jy prostaatprobleme het of sukkel om uriene te produseer
- jy jig gehad het
- jy ’n abnormale bloedtoestand het
- jy enige bloed- of oriëntoetse moet ondergaan.

#### Ander medisyne en Furosemide 40 Biotech

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- medisyne om bloeddruk te verlaag, soos ACE-remmers, renien-inhibeerders, alfablokkers, kalsiumkanaalblokkeerders, diuretika, fenotiasiene
- medisyne om geestesongesteldheid te behandel (bv. pimoziëd, amisulpried, sertindol)
- medisyne vir disritmieë (bv. sotalol, amidaroon, flekainied)
- digoksien vir jou hart
- moxisylte vir Raynaud se sindroom
- nitrate (vir angina)
- litium vir depressie of manie
- sukraalfaat vir maagsere
- cholestyramien of kolestipol vir hoë cholesterol
- nie-steroidale anti-inflammatoriese middels (NSAIDs) bv. ibuprofeen of naprokseen
- aspirien vir pyn
- antibiotika vir infeksies wat jou niere of ore aantas (bv. cefaclor, colistien, gentamisien, vankomisien)
- antidepressante (bv. monoamienoksidase-inhibeerders (MAOI’s))
- medisyne om diabetes te beheer soos insulien of tablette
- anti-epileptika bv. fenitoin of karbamasepien
- amfoterisien (om swaminfeksies te behandel)
- kortikosteroïede of antihistamiene (om allergiese reaksies te behandel)
- chloraalhidraat (om slapeloosheid te behandel)
- medisyne vir ADHD
- medisyne wat kanker behandel bv. aldesleukin
- levodopa (vir Parkinson se siekte)
- orale voorbehoedmiddels
- alprostadil vir erektile disfunksie
- sekere behandelings vir asma soos teofilien of salbutamol
- probenesied om jig te voorkom
- as jy op die punt staan om ’n prosedure te ondergaan waar curariforme spierverslappers (bv. vekuronium) of narkosemiddels gebruik kan word, vertel jou narkotiseur/ tandarts of gesondheidsorgverskaffer
- lakseermiddels wat oor ’n lang tydperk gebruik word
- medisyne of voedsel wat drop (liquorice) bevat

#### Furosemide 40 Biotech met kos en drank

Furosemide 40 Biotech kan ’n verhoogde hipotensiewe effek veroorsaak.

#### Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om ’n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.

Moenie Furosemide 40 Biotech gebruik as jy jou baba borsvoed nie.

#### Bestuur en gebruik van masjiene

Jy kan verminderde geestelike waaksaamheid ervaar.

Dit is nie altyd moontlik om te voorspel tot watter mate Furosemide 40 Biotech kan inneng met die daaglikse aktiwiteite van ’n pasiënt nie. Jy moet verseker dat jy nie by die bogenoemde aktiwiteite betrokke raak voordat jy bewus is van die mate waarin Furosemide 40 Biotech jou affekteer nie.

#### Furosemide 40 Biotech bevat laktose

As jy deur jou dokter gesê is dat jy ’n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie Furosemide 40 Biotech neem.

#### 3. Hoe om Furosemide 40 Biotech te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem Furosemide 40 Biotech altyd presies soos jou dokter of apteker vir jou gesê het. Gaan na jou dokter of apteker as jy nie seker is nie.

Die gewone aanvangsdosis is 40 mg in die oggend.

*Hoë bloeddruk:* 20-40 mg twee keer per dag.

Kinders ontvang gewoonlik daaglikse orale dosisse van 1 mg/kg liggaamsgewig. Indien nodig, kan hierdie dosis stap vir stap verhoog word tot ’n maksimum van 3 mg/kg liggaamsgewig per dag. ’n Dosis van 120 mg per dag moet nie met kinders oorskry word nie.

Jou dokter sal jou vertel hoe lank jou behandeling met Furosemide 40 Biotech sal duur.

As jy die indruk het dat die effek van Furosemide 40 Biotech te sterk of te swak is, vertel jou dokter of apteker.

#### As jy meer Furosemide 40 Biotech neem as wat jy moet

In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

#### As jy vergeet om Furosemide 40 Biotech te neem

Moenie ’n dubbeldosis neem om vergete individuele dosisse in te haal nie.

#### 4. Moontlike nuwe-effekte

Furosemide 40 Biotech kan nuwe-effekte hê. Nie alle nuwe-effekte wat vir Furosemide 40 Biotech aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy Furosemide 40 Biotech neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

#### As enige van die volgende gebeur, hou op om Furosemide 40 Biotech te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal
- uitslag of jeuk
- flou word

Hierdie is alles baie ernstige nuwe-effekte. As jy dit het, het jy dalk ’n ernstige reaksie op Furosemid 40 Biotech gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

#### Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:

- bloedafwykings, soos beenmurgonderdrukking
  - hartritmie, ’n skielike daling in bloeddruk wanneer jy uit ’n sittende of geneigde (lê) posisie staan
  - patent ductus arteriosus (PDA) is ’n aanhoudende opening tussen die twee groot bloedvate wat vanaf die hart van ’n baba lei
- Dit is alles ernstige nuwe-effekte. Jy benodig dalk dringende mediese hulp.

#### Vertel jou dokter as jy enige van die volgende opmerk:

*Gereelde nuwe-effekte:*

- dehidrasie, veranderde balans van vloeistof of chemikalieë in die liggaam (bv. natrium, kalium, chloor, kalsium en magnesium) wat ’n droë mond, swakheid, moegheid of lomerigheid, rusteloosheid, aanvalle, spierpyn, moegheid of krampe, lae bloeddruk veroorsaak, verlies van kon sentrasie en vertraagde reaksies, probleme om water uit te skei, vinnige of onreëlmatige hartklop en voel en siek wees
- ’n toestand wat voorkom wanneer die vlak van natrium in die bloed te laag is
- lae bloedvolume
- verhoogde kreatinien en bloedureum (gesien in bloedtoetse)
- die gevolg is van óf lae chloried-inname óf oormatige chloriedvermorsing
- te lae kalsiumvlakke in die bloed, te lae magnesium in die bloed
- abnormale lae vlak van die chloried-ioon in die bloed
- lighoofdigheid, sensasies van druk in die kop, hoofpyn, lomerigheid, swakheid, veranderinge in sig, droë mond, duiseligheid wanneer jy staan.
- ’n nierversteuring waarin ’n oormaat kalsium in die niere neergelê word
- kreatinien verhoog
- bloedureum verhoog

*Minder gereelde nuwe-effekte:*

- bloedafwykings bv. leukopenie, agranulositose, trombositopenie
- bloedarmoede wat moegheid, kortasem, ongewone bloeding of kneusing veroorsaak
- jig
- veranderinge in die liggaam gesien in toetse soos vlakke van cholesterol, glukose en uriensuur
- veranderinge in bloedselle soos hoeveelheid witbloedselle, vermindering van bloedplaatjies wat ’n uitslagkoors veroorsaak, sweet, moegheid en gewigsverlies. Jou dokter sal gereelde bloedtoetse uitvoer om te verseker dat geen veranderinge plaasgevind het nie
- droë mond, dors, voel of siek wees, veranderinge in dermbewegings insluitend diarree en hardlywigheid
- psigiatriese versteuring NOC wat delusies, hallusinasies, ongeorganiseerde spraak veroorsaak

- gevoel ’spelde en naalde’ of tintelende sensasie
- verwarring, hoofpyn, moegheid
- veranderinge in visie insluitend dowwe of geel visie
- doofheid (soms onomkeerbaar)
- ’tuit’ in die ore, gehoorverlies gewoonlik omkeerbaar
- simptome van skok soos veranderinge in hartklop, kortasem, koel klam vel
- droë mond, dors, naarheid, dermmotiliteitsversteurings, braking, diarree en hardly wigheid
- inflamasie van die pankreas wat pyn in jou buik of rug en naarheid veroorsaak
- veranderinge in die lewer wat vergeling van die vel of wit van die oë veroorsaak
- veluitslag
- fotosensitiwiteit, toksiese epidermale nekrolise (TEN) is ’n seldsame en ernstige veltoestand
- spierkrampe, swakheid
- inflamasie of mislukking van die nier wat rugpyn of veranderinge in die hoeveelheid of behoefte om te urineer kan veroorsaak
- verergering van toestande waar daar reeds balanse van vloeistof of chemikalieë in die liggaam is
- swelling tussen die nierbuisies
- ’n toestand waarin die niere skielik nie afval uit die bloed kan filtreer nie
- algemeen moeg, onwel, koors

*Die frekwensie van die volgende nuwe-effekte is onbekend:*

- alkalose behels ’n primêre toename in serumbikarbonaat (HCO3-) konsentrasie,
- uitskeiding van kalium
- duiseligheid, floute en verlies van bewussyn
- akute veralgemeende eksantematiese pustulose (AGEP) (akute febriele geneesmiddeluitbarsting)
- korwe, verskeie vorme van dermatitis, allergiese velreaksies
- ’n velafwyking wat gekenmerk word deur bul-oog-vormige letsels.
- ’n reaksie op medikasie wat begin met griepagtige simptome, gevolg deur ’n pylnike uitslag wat versprei en blase

Indien jy enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis.

#### Aanmelding van nuwe-effekte

As jy nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die **“6.04 Adverse Drug Reaction Reporting Form”**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur nuwe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van Furosemid 40 Biotech.

#### 5. Hoe om Furosemide 40 Biotech te bewaar

Bewaar buite bereik van kinders
Bewaar teen of benede 25 °C in ’n koel plek. Beskerm teen lig.
Moet nie gebruik na die vervaldatum soos aangedui op die etiket/ karton/ bottel nie
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

#### 6. Inhoud van die pakkie en ander inligting

#### Wat Furosemide 40 Biotech bevat

Elke kapsule bevat 40,0 mg van die aktiewe bestanddele furosemied. Die ander bestanddele is kolloïdale silikondioksied (Aerosil 200), gesuiwerde talk en laktose.

Die ander bestanddele is Elanco Opaque Blue 50, Brilliant Blue CI 42090 Erythrosine CI 45430, Elanco Opaque Wit, Gelatien, Titanium Dioxide CI 77891.

#### Hoe Furosemide 40 Biotech lyk en die inhoud van die verpakking

Ondeursigtige wit lyf/ondeursigtige turkooisblou doppie, grootte ‘2’ snap-pas kapsule wat wit, klont-vrye poeier bevat.

Furosemide 40 Biotech-kapsules is beskikbaar in deursigtige PVC/PVDC/Aluminium stulpstrookverpakings van 30 tablette. Elke stulpstrook bevat 10 kapsules en 3 stulpstrokies is in ’n buitekarton verpak.

Furosemide 40 Biotech word verpak as 30, 112, 250, 1000 en 5000 kapsules in ’n wit HDPE-houer.

Pasiëntgereed-pakkies (PRP’s) is beskikbaar in pakgroottes van 56 of 84 kapsules. Alle pakgroottes mag nie noodwendig op een slag bemark word nie.

#### Houer van Registrasiesertifikaat

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#### Hierdie pamflet is laas hersien in

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#### Registrasienommer

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