APPROVED PATIENT INFORMATION LEAFLET FOR HYFUTA

SCHEDULING STATUS:

S3

HYFUTA 20 mg/2 ml, Solution for injection or infusion

Furosemide

HYFUTA 100 mg/10 ml, Solution for injection or infusion

Furosemide

Each ml contains 10 mg furosemide.

"Contains no sugar"

Read all of this leaflet carefully before you Start taking **HYFUTA**

- 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.

What is in this leaflet

1.What HYFUTA is and what it is used for

The active substance is furosemide

HYFUTA belongs to a group of medicines called diuretics. It works in your kidneys to increase the amount of urine produced.

HYFUTA may be used to treat swelling of the ankles, feet, legs, brain, heart or lungs.

2.What you need to know before you use HYFUTA

HYFUTA should not be administered to you:

- If you are hypersensitive or (allergic) to **HYFUTA** or any of the other
- ingredients of **HYFUTA** (listed in section 6).
- if you have increased uraemia (high levels of waste products, normally excreted in the urine) and oliguria (urinate less than usual) during treatment of severe progressive kidney disease
- if your kidneys are failing or have stopped working due to liver coma
- if you have low levels of potassium or sodium salts or an imbalance of chemicals in your blood (shown in a blood test)
- if your blood volume is low (you may feel dizzy or faint or have pale skin) or if you are dehydrated
- if you have low blood pressure (dizziness or light-headedness)
- if you are unable to pass urine (anuria)
- if you previously received certain medicines that have damaged your kidneys or liver
- if you have severe liver problems (cirrhosis), affecting your consciousness
- if you have Addison's disease (a hormonal disorder causing you not to make enough cortisol and other hormones in your adrenal glands)
- if you have too much calcium in your blood
- if you are breastfeeding your baby (see section 4.6).

Warnings and precautions

Special care should be taken with **HYFUTA**

Tell your doctor or healthcare provider:

- if you have kidney problems or difficulty passing urine (for example caused by a large prostate gland)
- if you have low blood pressure (hypotension)
- if you have liver problems
- if you have diabetes
- if you have gout
- if you have adrenal disease
- if you have heart failure
- if you are elderly you may be more liable to electrolyte deficiency. Your sodium and potassium levels must be regularly monitored and corrected if necessary by supplements and a potassium rich diet. Calcium and magnesium levels should also be monitored.
- if you are dehydrated
- if you are taking medicines such as cardiac glycosides or steroids
- if you are an elderly person who also takes risperidone
- if you are on a low sodium diet, as you may lose too much water and get low blood pressure.
- if you experience ringing in the ears or hearing loss

Other medicines and HYFUTA

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

- other diuretics that help you pass more urine
- if you are taking any medicines that can be harmful to your kidneys
- antifungal medicines such as amphotericin
- heart medicines to help your heart beat (e.g. digoxin) or to help your heart beat

regularly (such as amiodarone, sotalol)

- lithium – this medicine may be used to treat mood swings and some forms of depression
- risperidone used in elderly persons with dementia
- laxatives
- medicines for diabetes
- cancer medicines, such as cisplatin
- certain antihistamines
- medicines used to relax your muscles before or during surgery (such as atracurium)
- ciclosporin (may be used to prevent organ rejection)
- muscle relaxants such as tubocurarine
- medicines for depression (such as reboxetine)
- nonsteroidal anti-inflammatory medicines (NSAIDs) for pain and inflammation
- sedatives, pain or sleeping tablets containing barbiturates
- narcotic type painkillers e.g. codeine
- corticosteroids
- medicines for stomach ulcer healing (such as ranitidine)
- medicines to lower your blood pressure, as their effect may be enhanced
- medicines used for epilepsy (such as carbamazepine, phenytoin)
- warfarin (to thin your blood).
- probenecid (for gout)
- chloral hydrate (sedative)
- levodopa
- laxatives
- nitrates
- prostaglandins
- sympathomimetics
- theophylline

- medicines that cause QT prolongation (change the rhythm of the heart)

Pregnancy, breastfeeding and fertility

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or nurse for advice before taking this medicine. **HYFUTA** passes through the placenta and hence should not be given during pregnancy unless doctor feels it extremely necessary. If it is given in cases of swelling or water retention, the growth of the baby must be regularly monitored.

Breastfeeding

HYFUTA passes into the milk and may inhibit secretion of milk. Hence it should be avoided in breast-feeding women.

Driving and using machines

It is not always possible to predict to what extent **HYFUTA** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **HYFUTA** affects them.

HYFUTA may make you feel dizzy and affect your ability to concentrate**.** Do not drive or use tools or machines if you are affected by the administration **of HYFUTA.**

3. How to receive HYFUTA

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

You will not be expected to give yourself **HYFUTA**. It will be given to you by a person who is qualified to do so.

Your doctor will work out your dose of **HYFUTA** to be given and how many times the dose must be repeated.

HYFUTA is normally given into a vein (intravenously) or into a muscle (intramuscularly).

If you receive more HYFUTA than you should

Since your health care provider will administer **HYFUTA**, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

4. Possible side effects

HYFUTA can have side effects.

Not all side effects reported for **HYFUTA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **HYFUTA**, please consult your health care provider for advice.

If any of the of the following happens, stop taking **[PRODUCTNAME]** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the ankles or legs, face, lip, tongue, or throat, 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 **HYFUTA**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- yellowing of the eyes or skin, stomach pain, nausea; dark coloured urine; these may be signs of jaundice or inflammation of the pancreas
- pain on the kidneys, blood in the urine and fever
- change in the way your heart beats, for example, if it starts beating faster or slower

- severe skin conditions such as bullous lesion, acute generalised exanthematous pustulosis

- acute generalised exanthematous pustulosis (AGEP) and drug rash with eosinophilia syndrome (characterised by severe allergic reaction, accompanied by fever and blisters on the skin, peeling of the skin and tiny spots from bleeding in the skin).

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:

- 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
- metabolic acidosis (characterised by chest pain, irregular heartbeat, nausea, vomiting or unusual weakness/tiredness).

Less frequent side effects:

- elevated quantity of cholesterol in your blood
- insomnia (difficulty sleeping)
- heart complaints e.g., irregular heartbeat and heart failure
- headache, dizziness
- cough
- constipation
- low blood pressure
- vomiting
- abnormal functioning of your kidney
- rash
- itching
- back pain

- feeling weak
- muscle spasm
- increased urea level in the blood
- increased creatinine blood levels which may indicate

Less frequent side effects:

- skin rash and sensitivity to light (photosensitivity)
- gout attacks (aching or swollen joints), an abnormally high level of uric acid in the blood
- (hyperuricaemia)
- headache, paraesthesia (feeling of tingling, burning or numbness of the skin with no apparent reason), fainting
- high blood sugar
- high levels of sugar in your urine (glycosuria) which is characterised by extreme hunger, extreme thirst or dehydration, accidental urination or more frequent urination
- passing urine more often than normal (leading to an excessive depletion of body fluids and calcium)
- hypovolaemia (when the liquid portion of your blood (plasma) is too low, caused by vomiting, diarrhoea or excessive bleeding), dehydration (especially if your are elderly, characterised by increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, stomach upsets or uneven heartbeats)
- dizziness, headache, paraesthesia (an abnormal sensation, typically tingling or prickling), syncope (loss of consciousness caused by a fall in blood pressure)
- low blood pressure which may cause dizziness when standing up
- bone marrow depression (a decrease in bone marrow activity, resulting in reduced production of blood cells)
- serious blood problems (characterised by bruising more easily or bleeding, getting

more infections (e.g. sore throat, mouth ulcers, fever), feeling weak or tired more than usually).

- eosinophilia (increase in certain white blood cells)
- low sodium blood levels
- dehydration
- elevated quantity of triglycerides (fats) in your blood
- fast heart beat
- inflammation of the gall bladder
- decreased blood pressure that can cause dizziness upon standing
- thrombosis (blood clot) in the leg
- sore throat
- flatulence
- underactive thyroid
- increase in blood glucose
- reduced sense of touch
- increased sweating
- musculoskeletal pain
- feeling generally unwell
- kidney inflammation
- enlargement of breasts in men
- changes in some blood test results

Frequency not known:

- blurred or yellow vision
- hearing problems, such as deafness or ringing in the ears
- muscle pain and cramps or spasms
- nausea (feeling sick), vomiting, diarrhoea
- tiredness, irritated skin, pain at the injection site and fever

- stomach pain, nausea and vomiting (pancreatitis)
- a heart defect in premature babies found in the days or weeks after birth (patent ductus arteriosus)
- inflammation of blood vessels (vasculitis)
- difficulty urinating and completely emptying your bladder (if you have a bladder emptying disorder, an enlarged prostate gland or restricted urinary flow)
- low levels of thiamine (vitamin B1) (characterised by loss of appetite, weakness, pain in the limbs, shortness of breath and swollen feet or legs)
- high levels of cholesterol or triglycerides (fats) in your blood.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **HYFUTA**.

5. How to store HYFUTA

- Store in a refrigerator (2 °C to 8 °C). Do not freeze the reconstituted and diluted solution.
- Store all medicines out of reach of children.
- Protect form light.
- Keep the vial in the outer carton until required for use.
- The reconstituted final medicines solution is stable for 24 hours at ambient room temperature at or below 25 °C (77 °F), must be refrigerated at 2 °C to 8 °C (36 °F to

46 °F).

- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / vial.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

For single use only. Discard any unused contents.

6. Contents of the pack and other information

What HYFUTA contains

- The active substance is Furosemide

What HYFUTA looks like and contents of the pack

HYFUTA 20 mg/2 ml (10 mg/ml)

2 ml amber tubular glass vial with a rubber stopper and flip off seal.

Pack size: 21 x 1's

HYFUTA 100 mg/10 ml (10 mg/ml)

10 ml amber tubular glass vial with a rubber stopper and flip off seal.

Pack size:1x 1's

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus

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HYFUTA 20 mg/2 ml: 57/18.1/0455.453

HYFUTA 100 mg/10 ml: 57/18.1/0456.454

Access to the corresponding Professional Information

Hetero Drugs South Africa (Pty) Ltd.,

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