PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

INSPRA® 25 Tablets

INSPRA® 50 Tablets

Eplerenone

Contains sugar (lactose monohydrate)

Each INSPRA 25 tablet contains 35,7 mg lactose monohydrate.

Each INSPRA 50 tablet contains 71,4 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking INSPRA

- 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.
- INSPRA 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 INSPRA is and what it is used for

INSPRA belongs to a group of medicines known as selective aldosterone blocking medicines. These

medicines inhibit the action of aldosterone, a substance produced within the body, which controls your blood pressure and heart function. High levels of aldosterone can cause changes in your body that lead to heart failure.

INSPRA is used to reduce the risk of cardiac death or heart failure in patients who have suffered a heart attack.

2. What you need to know before you take INSPRA

Do not take INSPRA

- If you are hypersensitive (allergic) to eplerenone or any of the other ingredients of INSPRA (listed in section 6).
- If you have high levels of potassium in your blood (hyperkalaemia).
- If you are taking potassium sparing diuretics (certain types of water tablets) or “salt tablets” (potassium supplements).
- If you are taking medicines that are used to treat fungal infections (e.g. ketoconazole or itraconazole).
- If you are taking antiviral medicines that are used to treat HIV infections (e.g. ritonavir).
- If you have moderate to severe kidney disease.
- If you have severe liver disease.

Warnings and precautions

Take special care with INSPRA:

- If you have kidney or liver disease.
- If you have type 2 diabetes mellitus (a condition where your blood sugar becomes too high).
- If you are taking salt tablets and medicines for high blood pressure or heart disease (angiotensin converting enzyme (ACE) inhibitors and/or angiotensin receptor blockers (ARB)).
- If you are taking lithium (for mania/depression, also called bipolar disorder), nonsteroidal anti-inflammatory drugs (NSAIDs – aspirin type pain killers).
- If you are taking erythromycin (a medicine to treat bacterial infections), saquinavir (an antiviral medicine used for HIV treatment) or fluconazole (an antifungal medicine) as the dosage you have been prescribed may need to change.

Children

INSPRA should not be used in children as the safety and effectiveness has not been established.

Other medicines and INSPRA

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

Some medicines can affect the way other medicines work. Your doctor may need to adjust the amount of INSPRA or other medicines you are taking.

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

- Ketoconazole, itraconazole or fluconazole (used to treat fungal infections).
- Verapamil (for heart problems and high blood pressure).
- ACE inhibitors and/or angiotensin receptor blockers (ARBs) (used to treat high blood pressure, heart problems or some kidney conditions).
- Potassium sparing diuretics (certain water tablets used to treat fluid retention).
- Potassium supplements (salt tablets).
- Saquinavir or ritonavir (antivirals for treating HIV).
- Erythromycin (used to treat bacterial infections).
- Lithium (for treating mania/depression; also called bipolar disorder).
- Non-steroidal anti-inflammatory drugs (NSAIDs – aspirin type pain killers).
- St John's Wort (a herbal medicine used to treat depression and other conditions).

INSPRA with food and drink

INSPRA may be taken with or after a meal or on an empty stomach.

Swallow the tablets with a glass of water.

Pregnancy and breastfeeding

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 health care provider for advice before taking this medicine.

Do not take INSPRA if you are pregnant or breastfeeding your baby.

Driving and using machines

You may feel dizzy or faint after taking this medicine. If this happens, do not drive or use dangerous

machinery.

It is not always possible to predict to what extent INSPRA 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 INSPRA affects them.

INSPRA contains lactose monohydrate

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

3. How to take INSPRA

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

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

Following a heart attack, INSPRA is usually given in combination with standard medicines. The usual dose is 50 mg given once a day, starting at 25 mg and slowly increasing to 50 mg in about 4 weeks.

Your doctor will tell you how long your treatment with INSPRA will last. Do not stop treatment early.

If you have the impression that the effect of INSPRA is too strong or too weak, tell your doctor or pharmacist.

If you take more INSPRA than you should

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

If you accidentally take too many tablets, you may feel dizzy.

If you forget to take INSPRA

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

4. Possible side effects

INSPRA can have side effects.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection.
- High levels of potassium in the blood.
- Dehydration.
- Dizziness.
- Fainting.
- Heart attack.
- Low blood pressure.
- Cough.
- Diarrhoea.
- Nausea.
- Constipation.
- Itching.
- Muscle cramps and pain.
- Abnormal kidney function.
- Increased blood urea levels.

Less frequent side effects:

- Sore throat.
- An increase in the number of eosinophilic blood cells and leucocytes (specific sorts of white blood cells).
- Underactive thyroid (a condition in which the thyroid gland does not produce enough thyroid hormone causing a number of symptoms such as tiredness, poor ability to tolerate cold and weight gain).
- Elevated quantity of cholesterol or triglycerides (fats) in your blood.
- Low sodium blood levels.
- Difficulty sleeping.
- Reduced sense of touch.

- Headache.
- Heart complaints e.g. irregular heartbeat and heart failure.
- Decreased blood pressure that can cause dizziness upon standing.
- Flatulence.
- Vomiting.
- Inflammation of the gall bladder.
- Increased sweating.
- Back pain.
- Leg cramps.
- Feeling weak.
- Physical weakness or lack of energy, feeling generally unwell.
- Increased creatinine blood levels which may indicate kidney problems and kidney inflammation.
- Increase in blood glucose.

Other side effects:

- Rash and swollen face, tongue or throat.
- Difficulty swallowing.
- Hives and difficulty breathing which are symptoms of angioneurotic oedema.

If any of these side effects occur, are severe or bother you, tell your doctor or pharmacist.

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 Reactions 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 INSPRA.

5. How to store INSPRA

- Store all medicines out of reach of children.
- Store at or below 30 °C in a cool dry place.

- Store in the original package.
- Keep the blister in the outer carton.
- Protect from light/moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the blister/carton.
- 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 INSPRA contains

The active substance is eplerenone.

INSPRA 25: Each tablet contains 25 mg eplerenone.

INSPRA 50: Each tablet contains 50 mg eplerenone.

The other ingredients are croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry Yellow, sodium laurilsulfate and talc (asbestos-free).

What INSPRA looks like and contents of the pack

INSPRA 25: A yellow, debossed, arc diamond, film-coated tablet, stylised “Pfizer” on one side of the tablet and “NSR” over “25” on the other side of the tablet.

INSPRA 50: A yellow, debossed, arc diamond, film-coated tablet, stylised “Pfizer” on one side of tablet and “NSR” over “50” on the other side of the tablet.

INSPRA tablets are available in cardboard cartons of 30, 60 or 90 tablets containing aluminium foil/opaque PVC blister strips each of 10 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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