

**Patient package insert according to Pharmacists' Regulations (Preparations) – 1986**

This medicine can be sold with a physician's prescription only

## **Inspra<sup>®</sup> 25, 50 mg, film-coated tablets**

Each tablet contains 25 mg or 50 mg eplerenone respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar to yours.

### **1. What is the medicine intended for?**

- In addition to the standard treatment including beta blockers, to reduce the risk of cardiovascular mortality and morbidity in stable patients with left ventricular dysfunction (ejection fraction equal to or smaller than 40%) and clinical evidence of heart failure after a recent myocardial infarction.
- In addition to the standard optimal treatment, to reduce the risk of cardiovascular mortality and morbidity in patients with chronic heart failure with NYHA class II and left ventricular systolic dysfunction (ejection fraction equal to or smaller than 30%).

**Therapeutic group:** selective aldosterone antagonist.

### **2. Before using the medicine**

**Do not use the medicine if:**

- You are hypersensitive (allergic) to the active ingredient (eplerenone), or to any of the other ingredients this medicine contains (see section 6).
- You suffer from high levels of potassium in the blood (hyperkalemia).
- You are taking medicines of the potassium-sparing diuretics group.
- You suffer from a severe kidney disease.
- You suffer from a severe liver disease.
- You are taking medicines for treatment of fungal infection (ketoconazole or itraconazole).
- You are taking antiviral medicines for treatment of HIV (ritonavir or nelfinavir).
- You are taking an antibiotic for treatment of bacterial infections (telithromycin or clarithromycin).
- You are taking nefazodone for treatment of depression.
- You are taking medicines for treatment of certain heart diseases or for treatment of hypertension, called angiotensin converting enzyme inhibitors (ACE inhibitors) together with angiotensin receptor blockers (ARB).

#### **Special warnings regarding the use of the medicine**

**Before the treatment with Inspra, tell the doctor if:**

- You suffer from a kidney or liver disease (see also "Do not use the medicine if").
- You are taking lithium (usually given for treatment of manic-depressive disorder, also called bipolar disorder).
- You are taking tacrolimus or cyclosporine (medicines given for treatment of certain skin diseases such as psoriasis or eczema and for prevention of organ rejection after transplantation).

#### **Children and adolescents**

No information is available regarding the safety and efficacy of using this medicine in children and adolescents.

## Tests and follow-up

Blood potassium levels should be measured before starting treatment with **Inspra**, during the first week of treatment and one month after starting treatment or after a change in dosage. The dosage will be adjusted by your doctor according to the potassium levels in the blood.

## Drug interactions

**If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.**

Especially if you are taking:

- Itraconazole or ketoconazole (for treatment of fungal infections), ritonavir, nelfinavir (antiviral medicines for treatment of HIV infection), clarithromycin, telithromycin (for treatment of bacterial infections) or nefazodone (for treatment of depression), since these medicines reduce the breakdown of **Inspra**, thereby prolonging its effect on the body.
- Potassium-sparing diuretics and potassium supplements, since these medicines increase the risk of high levels of potassium in the blood.
- Angiotensin converting enzyme inhibitors (ACE inhibitors) and angiotensin receptor blockers (ARB) (used for treatment of high blood pressure, heart disease or certain kidney diseases), since the combination of these medicines may increase the risk of high levels of potassium in the blood.
- Lithium (usually given for treatment of manic-depressive disorder, also called bipolar disorder). Use of lithium in combination with diuretics and ACE inhibitors (for treatment of high blood pressure and heart disease) has been shown to cause levels of lithium in the blood to become too high and may cause side effects of: loss of appetite, visual impairment, tiredness, muscle weakness, muscle spasms.
- Cyclosporine or tacrolimus (medicines given for treatment of certain skin diseases such as psoriasis or eczema or for prevention of organ rejection after transplantation). These medicines may cause kidney problems, thereby increasing the risk of high potassium levels in the blood.
- Non-steroidal anti-inflammatory medicines (NSAIDs – certain analgesics such as ibuprofen used to relieve pain, stiffness and inflammation). These medicines may cause kidney problems, thereby increasing the risk of high potassium levels in the blood.
- Trimethoprim (for treatment of bacterial infections) may increase the risk of high potassium levels in the blood.
- Alpha 1 receptor blockers such as prazosin or alfuzosin (for treatment of high blood pressure and certain prostate gland conditions) may lead to a drop in blood pressure and dizziness when standing up.
- Tricyclic antidepressants, such as amoxapine or amitriptyline (for treatment of depression), antipsychotic medicines (also known as neuroleptics) such as chlorpromazine or haloperidol (for treatment of psychiatric disorders), amifostine (given during chemotherapy treatments) and baclofen (for treatment of muscle spasms). These medicines may lead to a drop in blood pressure and dizziness when standing up.
- Glucocorticoids such as hydrocortisone or prednisone (for treatment of inflammations and certain skin diseases) and tetracosactide (mainly used for diagnosing and treatment of various disorders of the adrenal cortex), may decrease the effect of **Inspra** on lowering blood pressure.
- Digoxin (for treatment of certain heart problems). The levels of digoxin in the blood may increase when taken in combination with **Inspra**.
- Warfarin (anticoagulant): caution should be exercised when taking warfarin, since high levels of warfarin in the blood may cause changes in the effect of **Inspra** on the body.
- Erythromycin (an antibiotic for treatment of bacterial infections), saquinavir (an antiviral medicine for treatment of HIV), fluconazole (for treatment of fungal infections), amiodarone, diltiazem and verapamil (for treatment of heart problems and high blood pressure) reduce the breakdown of **Inspra**, and thereby may prolong the duration of the effect of **Inspra** on the body.
- St. John's Wort (herbal preparation), rifampicin (for treatment of bacterial infections), carbamazepine, phenytoin and phenobarbital (for treatment of epilepsy, among other things) may increase the breakdown of **Inspra**, thereby decreasing its effect.

### **Use of the medicine and food**

The medicine may be taken with or without food.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before using this medicine. The effect of **Inspra** has not been tested during pregnancy in humans.

It is not known whether eplerenone is excreted into breast milk. A decision should be made together with your doctor, whether to discontinue breastfeeding or discontinue taking the medicine.

### **Driving and using machines**

You may feel dizziness after taking **Inspra**. If this happens to you, do not drive or operate machinery.

### **Important information about some of the ingredients of the medicine**

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, essentially "sodium-free".

## **3. How to use the medicine?**

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

**Do not exceed the recommended dose.**

### **Method of administration**

The medicine may be taken with food or on an empty stomach. The tablet should be swallowed whole with plenty of water.

Do not crush/halve/chew, since the tablet is film-coated.

### **If you have accidentally taken a higher dosage**

If you have taken too much of the medicine, the most likely symptoms will be low blood pressure (manifested by dizziness, blurred vision, weakness, acute loss of consciousness) or hyperkalemia – high levels of potassium in the blood (manifested by muscle spasms, diarrhea, nausea, dizziness and headache).

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

### **If you forgot to take the medicine**

If you forgot to take this medicine at the designated time and it is time to take your next tablet, skip the forgotten tablet and take the next tablet on time. Otherwise, take the tablet as soon as you remember, as long as there is an interval of more than 12 hours until taking the next tablet. Afterwards, go back to taking the medicine as usual.

Do not take a double dose in order to compensate for the forgotten dose.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions on the use of this medicine, consult the doctor or pharmacist.**

## **4. Side effects**

Like any medicine, the use of **Inspra** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

### **Seek medical treatment immediately in case of:**

- Swelling of the face, tongue or throat
- Difficulty swallowing
- Hives and breathing difficulties

These are symptoms of angioneurotic oedema, an uncommon side effect that occurs in 1-10 users out of 1,000.

### **Additional side effects**

**Common side effects** (effects that occur in 1-10 out of 100 users):

- High levels of potassium in the blood (symptoms include muscle cramps, diarrhea, nausea, dizziness or headache)
- Fainting
- Dizziness
- Increased quantity of cholesterol in the blood
- Sleeplessness (insomnia)
- Headache
- Heart-related problems such as irregular heartbeat and heart failure
- Cough
- Constipation
- Low blood pressure
- Diarrhea
- Nausea
- Vomiting
- Kidney function disorders
- Rash
- Itch
- Back pain
- Feeling weak
- Muscle spasms
- Increased levels of urea in the blood
- Increased levels of creatinine in the blood, which may indicate kidney problems

**Uncommon side effects** (effects that occur in 1-10 out of 1,000 users):

- Infection
- Eosinophilia (a rise in certain white blood cells)
- Low sodium blood levels
- Dehydration
- Increased levels of triglycerides (fat) in the blood
- Fast heartbeat
- Gallbladder inflammation
- A drop in blood pressure which may cause dizziness when standing up
- Thrombosis (blood clot) in the leg
- Sore throat
- Flatulence
- Underactive thyroid gland
- Increased levels of glucose in the blood
- Decreased sensation to touch
- Increased sweating
- Muscle and bone pain
- Generally feeling unwell
- Inflammation of the kidney

- Enlarged breasts in men
- Changes in the results of certain blood tests

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.**

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (EXP) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store the medicine at a temperature below 25°C.

## **6. Additional information**

**In addition to the active ingredient, the medicine also contains:**

Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hypromellose, sodium lauryl sulfate, talc, magnesium stearate, titanium dioxide, macrogol 400, polysorbate 80, iron oxide yellow, iron oxide red.

**What the medicine looks like and what the package contains:**

**Inspra 25 mg:** a yellow, film-coated tablet, debossed with "VLE" on one side and with "NSR" and "25" on the other side.

**Inspra 50 mg:** a yellow, film-coated tablet, debossed with "VLE" on one side and with "NSR" and "50" on the other side.

Approved package sizes: 10, 20, 28, 30, 50, 100, 200 tablets. Not all package sizes may be marketed.

Revised in February 2025 according to MOH guidelines.

**Drug registration number at the national drug registry of the Ministry of Health:**

**Inspra 25 mg:** 134-67-31192

**Inspra 50 mg:** 134-68-31193

**Manufacturer and registration holder:** Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel