

INSpra™ FILM-COATED TABLET

Eplerenone (25 mg, 50 mg)

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What Inspra is used for

Inspra is used in combination with other drugs to help prevent worsening of dysfunction of the left lower chamber of the heart. It is also used when there is clinical evidence of heart failure after a recent heart attack.

How Inspra works

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

Before you use Inspra

- When you must not use it

Do not take Inspra

- if you are allergic (hypersensitive) to eplerenone or any of the other ingredients of Inspra.
- if you have high levels of potassium in your blood (hyperkalemia) or any other conditions associated with high potassium levels.
- if you are taking groups of drugs which help you to excrete excessive body fluid (potassium sparing diuretics) or potent inhibitors of CYP3A4 such as ketoconazole, itraconazole, and ritonavir.

- if you have moderate to severe kidney disease.
- if you have severe liver disease.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. The effect of Inspra has not been evaluated during pregnancy in humans.

It is not known if eplerenone is excreted in human breast milk. A decision should be made with your doctor, whether to discontinue breast-feeding or to discontinue the drug.

- Before you start to use it

Take special care with Inspra

- if you have high potassium levels in your blood
- if you have kidney or liver disease
- if you are in your old age (needs monitoring of potassium levels)

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You must not take Inspra with the following medications:

- Strong CYP3A4 inhibitors such as itraconazole or ketoconazole (used to treat fungal infections), ritonavir, nelfinavir (antiviral medication for treating HIV), clarithromycin, telithromycin (used to treat bacterial infections) or nefazodone (used to treat depression).
- Potassium sparing diuretics (drugs which help you to excrete excess body fluid) and potassium supplements (salt tablets).
- Angiotensin converting enzyme (ACE) inhibitors and angiotensin

receptor blockers (ARB) together (which are used to treat high blood pressure, heart disease or particular kidney conditions).

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

- Lithium (usually given for manic depressive disorder, also called bipolar disorder).
- Cyclosporin or tacrolimus (used to treat skin conditions such as psoriasis or eczema, and to prevent rejection after organ transplantation).
- Non-steroidal anti-inflammatory drugs (NSAIDs - certain pain killers, used to relieve pain, stiffness and inflammation).
- Trimethoprim (used to treat bacterial infections).
- Alpha1 blockers, such as prazosin or alfuzosin (used to treat high blood pressure and particular prostate conditions).
- Tricyclic antidepressants (for treatment of depression), antipsychotics (also known as neuroleptics used for the treatment of psychiatric disorders), amifostine (used during cancer chemotherapy) and baclofen (used to treat muscle spasm).
- Glucocorticoids (used to treat inflammation and certain skin conditions) and tetracosactide (mainly used for diagnosing and treating disorders of the adrenal cortex).
- Digoxin (used in the treatment of heart conditions).
- Warfarin (an anti-clotting drug).
- Mild to moderate CYP3A4 inhibitors such as erythromycin (used to treat bacterial infections), saquinavir (antiviral medication for treating HIV), fluconazole (used to treat fungal infections), amiodarone, diltiazem and verapamil (for the treatment of heart problems and high blood pressure).

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- CYP3A4 inducers such as St. John's Wort (herbal medicinal product), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin, and phenobarbital (used, among others, to treat epilepsy).

How to use Inspra

- How much to use

Inspra is usually administered together with other medication for heart failure e.g., beta blockers. The recommended maintenance dose is 50 mg once daily (OD). Treatment should be initiated at 25 mg once daily and titrated to the target dose of 50 mg once daily preferably within 4 weeks, taking into account the blood potassium levels. Inspra should usually be started within 3-14 days after a heart attack.

Blood potassium levels should be measured before starting Inspra therapy, within the first week and at one month after the start of treatment or after a change in dose. The dose may be adjusted by your doctor, depending on the potassium levels in your blood.

If you are receiving a group of medicines called mild to moderate CYP3A4 inhibitors, such as erythromycin, saquinavir, verapamil, and fluconazole, you should receive the dose of 25 mg once daily.

If you have mild kidney disease, you should start on one 25 mg tablet every day. And if you have moderate kidney disease, you should start on one 25 mg tablet every other day. These doses may be adjusted as needed based on your doctor's assessment and your blood potassium levels. In individuals with severe kidney disease, Inspra is not recommended.

In individuals with mild-to-moderate liver disease, no adjustment of the starting dose is required. If you have liver or kidney problems, you may need more frequent testing of your blood potassium levels.

For the elderly: No adjustment of the starting dose is required. Your doctor may perform frequent monitoring of your blood potassium levels.

Use in children: Safety and efficacy of eplerenone has not been studied in children with heart failure.

- When to use it

Always take Inspra exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Inspra tablets may be taken together with food or on an empty stomach. Swallow the tablets whole with plenty of water.

- How long to use it

It is important to keep taking Inspra as prescribed unless your doctor tells you to stop your treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

If it is almost time for your next tablet, skip the tablet you missed and take your next tablet when it is due.

Otherwise take the tablet as soon as you remember, providing there is more than 12 hours to when you are due to take your next tablet. Then go back to taking your medicine as you would normally. Do not take a double dose to make up for the forgotten tablet.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you have taken too much of your medicine, the most likely symptoms will be low blood pressure (expressed as a light feeling in your head, dizziness, blurred vision, weakness, acute loss of consciousness) or hyperkalemia, high levels of potassium in the blood (expressed by muscle cramps, diarrhoea, nausea, dizziness or headache).

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Inspra.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Inspra to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving or using machines

You may feel dizzy after taking Inspra. If this should happen, do

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not drive or operate machinery.

Important information about some of the ingredients of Inspira:

One of the ingredients of Inspira is lactose monohydrate (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Side Effects

Like all medicines Inspira can cause side effects, although not everybody gets them. If you experience any of the following:

Common side-effects (occurs between 1 and 10 out of every 100 patients):

- heart attack
- elevated potassium level in your blood
- dizziness
- fainting
- infection
- dehydration
- cough
- constipation
- low blood pressure
- diarrhoea
- nausea
- abnormal functioning of your kidney
- itching
- muscle spasm and pain
- increased urea level in the blood

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Inspira

- Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not use Inspira film-coated tablets after the expiry date {EXP} stated on the pack and blister.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What Inspira looks like

The Inspira 25 mg tablet is a yellow film-coated tablet. They are marked with "VLE" printed on one side of tablet and "NSR" over "25" on the other side of tablet.

The Inspira 50 mg tablet is a yellow film-coated tablet. They are marked with "VLE" printed on one side of tablet and "NSR" over "50" on the other side of tablet.

Inspira 25 mg and 50 mg film-coated tablet are available in pack sizes of 30's or 50's with each blister strips containing 10 tablets each.

*Not all pack sizes may be marketed.

- Ingredients

- Active ingredient:

The active substance of Inspira film-coated tablets is eplerenone.

- Inactive ingredients:

Magnesium Stearate, Talc, Microcrystalline Cellulose, Hypromellose, Opadry Yellow YS-1-12524-A,

Lactose Monohydrate, Croscarmellose Sodium, Sodium Lauryl Sulfate

- MAL numbers

Inspira 25 mg tablets
MAL20081801ARZ
Inspira 50 mg tablets
MAL20081802ARZ

Manufacturer

Viartis Pharmaceuticals LLC
KM 1.9 Road 689
Vega Baja, Puerto Rico 00693

Product Registration Holder

Viartis Sdn Bhd
15-03 & 15-04, Level 15, Imazium,
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Selangor, Malaysia.

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