Package Leaflet: Information for the User

Inspra® 25 mg and 50 mg film-coated tablets

Eplerenone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 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.

Inspra is used to treat your heart failure to prevent worsening and reduce hospitalisations if you have:
1. had a recent heart attack, in combination with other drugs that are used to treat your heart failure, or
2. have persistent, mild symptoms despite the treatment you have been receiving so far.

2. What you need to know before you take Inspra

Do not take Inspra
- if you are allergic to eplerenone or any of the other ingredients of this medicine (listed in section 6).
- if you have high levels of potassium in your blood (hyperkalemia)
- if you are taking groups of drugs which help you to excrete excessive body fluid, (potassium sparing diuretics) or “salt tablets” (potassium supplements)
- if you have severe kidney disease
- if you have severe liver disease
- if you are taking medicines that are used to treat fungal infection (ketoconazole or itraconazole)
- if you are taking antiviral medication for treating HIV (nelfinavir or ritonavir)
- if you are taking antibiotics used to treat bacterial infections (clarithromycin or telithromycin)
- if you are taking nefazodone used to treat depression.
- if you are taking medicines used to treat certain heart conditions or hypertension (so called angiotensin converting enzyme (ACE) inhibitor and an angiotensin receptor blocker (ARB)) together.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Inspra.
- if you have kidney or liver disease (see also “Do not take **Inspra**”)
- if you are taking lithium (usually given for manic depressive disorder, also called bipolar disorder)
- if you are taking tacrolimus or cyclosporin (used to treat skin conditions such as psoriasis or eczema, and to prevent rejection after organ transplantation)

Children and adolescents
The safety and efficacy of eplerenone in children and adolescents have not been established.

Other medicines and Inspra
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You must not take **Inspra** with the following medications (see section “Do not take **Inspra**”):
- 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) as these drugs reduce the break-down of **Inspra**, thereby prolonging its effect on the body.
- Potassium sparing diuretics (drugs which help you to excrete excess body fluid) and potassium supplements (salt tablets) as these drugs increase the risk of high potassium levels in your blood.
- 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) as these drugs may increase the risk of high potassium levels in your blood.

Please inform your doctor if you are taking any of the following medicines:
- Lithium (usually given for manic depressive disorder, also called bipolar disorder). Use of lithium together with diuretics and ACE inhibitors (used to treat high blood pressure and heart disease) has been shown to cause levels of lithium in the blood to become too high, which may cause side effects of: loss of appetite; visual impairment; tiredness; muscle weakness; muscle twitches.
- Cyclosporin or tacrolimus (used to treat skin conditions such as psoriasis or eczema and to prevent rejection after organ transplantation). These drugs can cause kidney problems and therefore increase the risk of high potassium levels in your blood.
- Non-steroidal anti-inflammatory drugs (NSAIDs - certain pain killers such as ibuprofen, used to relieve pain, stiffness and inflammation). These drugs may lead to kidney problems and therefore increase the risk of high potassium levels in your blood.
- Trimethoprim (used to treat bacterial infections) may increase the risk of high potassium levels in your blood
- Alpha I blockers, such as prazosin or alfuzosin (used to treat high blood pressure and particular prostate conditions) may lead to a fall in blood pressure and dizziness upon standing
- Tricyclic antidepressants such as amitryptyline or amoxapine (for treatment of depressions), antipsychotics (also known as neuroleptics) such as chlorpromazine or haloperidol (for the treatment of psychiatric disorders), amifostine (used during cancer chemotherapy) and baclofen (used to treat muscle spasm). These drugs may lead to a fall in blood pressure and dizziness upon standing.
- Glucocorticoids, such as hydrocortisone or prednisone (used to treat inflammation and certain skin conditions) and tetracosactide (mainly used for diagnosing and treating disorders of the adrenal cortex) may reduce the blood pressure lowering effect of **Inspra**.
- Digoxin (used in the treatment of heart conditions). Digoxin blood levels may be increased when taken together with **Inspra**.
- Warfarin (an anti-clotting drug): Caution is warranted when taking warfarin because high levels of warfarin in the blood may cause changes in the effect of **Inspra** on the body.
- 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) reduce the break-down of **Inspra** thereby prolonging the effect of **Inspra** on the body.
- St John's Wort (herbal medicinal product), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin, and phenobarbital (used, among others, to treat epilepsy) may increase the break-down of **Inspra** and thus decrease its effect.

Inspra with food and drink
Inspra may be taken with or without food.

Pregnancy and Breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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.

Driving and using machines
You may feel dizzy after taking **Inspra**. If this should happen, do not drive or operate machinery.

Inspra contains lactose monohydrate
Inspra contains 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.

3. How to take Inspra

Always take this medicine exactly as your doctor or pharmacist has told you. 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.

Inspra is usually administered together with other medication for heart failure e.g. beta blockers. The usual starting dose is one 25 mg tablet once daily, increasing after about 4 weeks to 50 mg once daily (either as

one 50 mg tablet or two 25 mg tablets). The maximum dose regimen is 50 mg daily.

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 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 if your doctor recommends and according to your blood potassium levels.
In patients with severe kidney disease, **Inspra** is not recommended.
In patients 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 (see also "Do not take **Inspra**").
For the elderly: no adjustment of the starting dose is required.
For children and adolescents: **Inspra** is not recommended.

If you take more Inspra than you should
If you take more **Inspra** than you should, tell your doctor or pharmacist immediately. 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).

If you forget to take Inspra
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 stop taking Inspra
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.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

If you experience any of the following:
You should seek immediate medical attention
- swollen face, tongue or throat
- difficulty swallowing
- hives and difficulties breathing

These are the symptoms of angioneurotic oedema, an uncommon (affecting up to 1 in 100 people) side effect.

Other reported side effects include:
Common side-effects (may affect up to 1 in 10 people)
- elevated potassium level in your blood (symptoms include muscle cramps, diarrhoea, nausea, dizziness or headache)
- dizziness
- fainting
- elevated quantity of cholesterol in your blood
- insomnia (difficulty sleeping)
- headache
- heart complaints e.g., irregular heartbeat and heart failure
- cough
- constipation
- low blood pressure
- diarrhoea
- nausea
- 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 kidney problems

Uncommon side-effects (may affect up to 1 in 100 people)
- infection
- eosinophilia (increase in certain white blood cells)
- dehydration
- elevated quantity of triglycerides (fats) in your blood
- low sodium blood levels
- 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

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inspra

Keep this medicine out of the sight and reach of children.
This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label after EXP, on the carton after 'Termin ważności' and on the tablet blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Inspra contains
The active substance of **Inspra** film-coated tablets is eplerenone. Each tablet contains 25 mg or 50 mg of eplerenone.

Inspra 25 mg and 50 mg film-coated tablets also contain the following inactive ingredients: lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium (E468), hypromellose (E464), sodium laurilsulfate, talc (E553b) and magnesium stearate (E470b).

The opadry yellow coating of **Inspra** 25 mg and 50 mg film-coated tablets contains hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), iron oxide yellow (E172), iron oxide red (E172).

What Inspra looks like and contents of the pack

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

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

Inspra 25 mg and 50 mg film-coated tablet are available in opaque PVC/Al blister packs containing 30 tablets.

Manufacturers:
Pfizer PGM, Zone Industrielle-29 route des Industries, 37530 Pocé-sur-Cisse, France or Fareva Amboise, Zone Industrielle-29 route des Industries, 37530 Pocé-sur-Cisse, France

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

PPA Number:
PPA 465/297/1 Inspra 25mg film-coated tablets
PPA 465/297/2 Inspra 50mg film-coated tablets

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Inspra 25 mg and 50 mg film-coated tablets are authorised in the following Member States of the EEA under the tradename Inspra: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom

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