Package leaflet: Information for the user

Inspra® 25mg film-coated tablets
(eplerenone)

Your medicine is available using the above name but will be referred to as **Inspra** throughout this leaflet.

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)
- 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.

- 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.
- 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 amitriptyline 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 25mg tablet once daily, increasing after about 4 weeks to 50mg once daily (either as one 50mg tablet or two 25mg tablets).
The maximum dose regimen is 50mg 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 25mg tablet every day. And if you have moderate kidney disease, you should start on one 25mg 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)
- fainting
- dizziness
- 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)
- 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

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 carton and blister after EXP. The expiry date refers to the last day of that month.
If your doctor tells you to stop taking the tablets, return any unused tablets to the pharmacist.
If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return to your pharmacist who will advise you.
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 25mg of eplerenone.

The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium (E468), hypromellose (E464), sodium laurilsulfate, talc (E553b) and magnesium stearate (E470b)
Tablet coating: opadry yellow: hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), iron oxide yellow (E172) and iron oxide red (E172).

What Inspra looks like and contents of the pack
Inspra are yellow tablets marked with "NSR" over "25" on one side of the tablet.

Inspra is available in blister packs of 30 tablets.

Manufacturer
Manufactured by: Fareva Amboise, Zone Industrielle-29 route des Industries, 37530 Pocé-sur-Cisse, France.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.
PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.
Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA No: 1151/132/1

Leaflet issue and revision date (ref): 17.11.17

Inspra® is a registered trademark of C.P. Pharmaceuticals International C.V.

Inspra 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

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Inspra 25mg film-coated tablets
Reference No: 1151/132/1

Package leaflet: Information for the user

Inspra® 25mg film-coated tablets
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2. What you need to know before you take Inspra

Do not take Inspra

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- if you have high levels of potassium in your blood (hyperkalemia)
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- if you are taking antiviral medication for treating HIV (nelfinavir or ritonavir)
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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

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- 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

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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.

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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).

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If you stop taking Inspra

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

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4. Possible side effects

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Other reported side effects include:

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(may affect up to 1 in 10 people):
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- fainting
- dizziness
- 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)
- 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
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- sore throat
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Website: www.hpra.ie E-mail: medsafety@hpra.ie

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5. How to store Inspra

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6. Contents of the pack and other information

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

The other ingredients in the tablet core are:
lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium (E468), hypromellose (E464), sodium laurilsulfate, talc (E553b) and magnesium stearate (E470b).
The other ingredients in the Opadry yellow coating are:
hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), iron oxide yellow (E172) and iron oxide red (E172).

What Inspra looks like and contents of the pack
Inspra are yellow tablets marked "Pfizer" on one side and "NSR" over "25" on the other side of the tablet.

Inspra is available in blister packs of 30 film-coated tablets.

Manufacturer
Manufactured by: Pfizer PGM, Zone Industrielle-29 route des Industries, 37530 Pocé-sur-Cisse, France
or
NPIL Pharmaceuticals (UK) Ltd, Morpeth Plant, Whalton Road, Morpeth, Northumberland, NE61 3YA, UK.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.
PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.
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PPA No: 1151/132/1

Leaflet issue and revision date (ref): 17.11.17

Inspra® is a registered trademark of Pfizer Caribe Limited.

Inspra 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

Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Inspra 25mg film-coated tablets
Reference No: 1151/132/1