

PACKAGE LEAFLET: INFORMATION FOR THE USER  
**INSPIRA® 50 mg film-coated tablets**  
 (eplerenone)

Your medicine is known as INSPIRA® 50 mg film-coated tablets but will be referred to as Inspra throughout the following leaflet.

Information for other strength of Inspra also may be present in 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
2. What you need to know before you take Inspra
3. How to take Inspra
4. Possible side effects
5. How to store Inspra
6. Contents of the pack and other information

**1. WHAT INSPIRA 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 INSPIRA**

**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 1 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**

Inspra contains lactose (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.

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

**3. HOW TO TAKE INSPIRA**

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)
- 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE INSPIRA

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- This medicinal product does not require any special storage conditions.
- Do not use Inspra after the expiry date stated on the pack and blister. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Inspra contains

- Each film-coated tablet contains 50 mg of eplerenone as the active ingredient.
- Tablets also contain the following inactive ingredients: lactose monohydrate, microcrystalline cellulose (E460), croscarmellose sodium (E468), hypromellose (E464), Sodium laurilsulfate, magnesium stearate (E470b) and talc (E553b).
- The opadry yellow coating of Inspra 50 mg film-coated tablets contains hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), yellow iron oxide (E172), and red iron oxide (E172).

#### What Inspra looks like and contents of the pack

The Inspra tablet is a yellow diamond shape film-coated tablet. They are marked “NSR” over “50” on the one side and plain on other side of tablet.

Inspra is available in blister packs containing 30 tablets.

#### Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd., Chemilines House, Alperon Lane, Wembley, HA0 1DX.

#### Manufacturer

This product is manufactured by Pfizer PGM, Zone industrielle-29, route des industries, 37530 Pocé-sur-Cisse, France.

**POM** PL: 19488/1735

Leaflet revision date: 20 June 2023

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S1735 LEAFLET Inspra 20230620

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**EPLERENONE 50 mg film-coated tablets**

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**1. WHAT EPLERENONE TABLETS ARE AND WHAT THEY ARE USED FOR**

Eplerenone Tablets 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.

Eplerenone Tablets are 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 EPLERENONE TABLETS**

**Do not take Eplerenone Tablets**

- 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 Eplerenone Tablets.

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- 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 Eplerenone Tablets**

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 Eplerenone Tablets, 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.
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- 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.
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- 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.
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- Digoxin (used in the treatment of heart conditions). Digoxin blood levels may be increased when taken together with Eplerenone Tablets.
- 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 Eplerenone Tablets 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 Eplerenone Tablets thereby prolonging the effect of Eplerenone Tablets 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 Eplerenone Tablets and thus decrease its effect.

**Eplerenone Tablets with food and drink**

Eplerenone Tablets 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 Eplerenone Tablets 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 Eplerenone Tablets. If this should happen, do not drive or operate machinery.

**Eplerenone Tablets contains lactose**

Eplerenone Tablets contains lactose (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.

Eplerenone Tablets contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. HOW TO TAKE EPLERENONE TABLETS**

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

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

Eplerenone Tablets are 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 Eplerenone Tablets 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, Eplerenone Tablets are 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 Eplerenone Tablets").

For the elderly: no adjustment of the starting dose is required.

For children and adolescents: Eplerenone Tablets are not recommended.

#### **If you take more Eplerenone Tablets than you should**

If you take more Eplerenone Tablets 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 Eplerenone Tablets**

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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 Eplerenone Tablets**

It is important to keep taking Eplerenone Tablets 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)
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- insomnia (difficulty sleeping)
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- feeling weak
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- increased urea level in the blood
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#### **Uncommon side-effects** (may affect up to 1 in 100 people):

- infection
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- low sodium blood levels
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### **5. HOW TO STORE EPLERENONE TABLETS**

#### **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**

- This medicinal product does not require any special storage conditions.
- Do not use Eplerenone after the expiry date stated on the pack and blister. The expiry date refers to the last day of that month.
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- The opadry yellow coating of Eplerenone 50 mg film-coated tablets contains hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80 (E433), yellow iron oxide (E172), and red iron oxide (E172).

#### **What Eplerenone Tablets looks like and contents of the pack**

The Eplerenone tablet is a yellow diamond shape film-coated tablet. They are marked "NSR" over "50" on the one side and plain on other side of tablet.

Eplerenone is available in blister packs containing 30 tablets.

#### **Product Licence holder**

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#### **Manufacturer**

This product is manufactured by Pfizer PGM, Zone industrielle-29, route des industries, 37530 Poc e-sur-Cisse, France.

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