

APPROVED PATIENT INFORMATION LEAFLET FOR PLERINTRA

SCHEDULING STATUS

S4

PLERINTRA 25 mg (film-coated tablets)

PLERINTRA 50 mg (film-coated tablets)

Each film-coated tablet contains 25 mg of Eplerenone.

Each film-coated tablet contains 50 mg of Eplerenone

Contains sugar "lactose monohydrate"

PLERINTRA: contains 36,465 mg lactose monohydrate

PLERINTRA: contains 72,930mg lactose monohydrate

Read all of this leaflet carefully before you start taking

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- **PLERINTRA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

- 1.What **PLERINTRA** is and what it is used for
- 2.What you need to know before you take **PLERINTRA**
- 3.How to take **PLERINTRA**
- 4.Possible side effects
- 5.How to store **PLERINTRA**
- 6.Contents of the pack and other information

1.What PLERINTRA is and what it is used for

The active substance is eplerenone

Eplerenone belongs to a group of medicines called 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.

PLERINTRA is used to reduce the risk of cardiac death or heart failure in patients who have suffered a heart attack.

2.What you need to know before you take PLERINTRA

- If you are hypersensitive (allergic) to eplerenone or any of the other ingredients of **PLERINTRA** (listed in section 6).
- if you have high levels of potassium in your blood (hyperkalemia)
- if you are taking groups of medicines 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

Take special care with **PLERINTRA**

- if you have kidney or liver disease (see also “Do not take **PLERINTRA**)
- 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)

If you have type 2 diabetes mellitus (a condition where your blood sugar becomes too high).

Children and adolescents

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

Other medicines and PLERINTRA

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if:

- You are taking medicines that contain 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 medicines reduce the break-down of **PLERINTRA**, thereby prolonging its effect on the body.
- Potassium sparing diuretics (medicines which help you to excrete excess body fluid) and potassium supplements (salt tablets) as these medicines 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 medicines 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 the blood to become too high, which may cause side effects 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 medicines 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 medicines 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 medicines 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 **PLERINTRA**
- Digoxin (used in the treatment of heart conditions). Digoxin blood levels may be increased when taken together with **PLERINTRA**.
- Warfarin (an anti-clotting medicine): Caution is warranted when taking warfarin because high levels of warfarin in the blood may cause changes in the effect of **PLERINTRA** 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

PLERINTRA thereby prolonging the effect of **PLERINTRA** 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 **PLERINTRA** and thus decrease its effect.

PLERINTRA with food, drink and alcohol

PLERINTRA may be taken with or without food.

Pregnancy, breastfeeding and fertility

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 **PLERINTRA** has not been evaluated during pregnancy in humans.

You must not use **PLERINTRA** if you are pregnant or breastfeeding.

Driving and using machines

PLERINTRA may cause dizziness. Do not drive a car or operate machinery until you know how **PLERINTRA** affects you. It is not always possible to predict to what extent **PLERINTRA** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **PLERINTRA** affects them.

PLERINTRA contains lactose monohydrate

Patients with the rare hereditary conditions of lactose, fructose or galactose intolerance should not take **PLERINTRA**

PLERINTRA contains sodium

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

3. How to take PLERINTRA

Do not share medicines prescribed for you with any other person.

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

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

PLERINTRA 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.

If you take more PLERINTRA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you accidentally take too many tablets, you may feel dizzy.

If you forget to take PLERINTRA

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

PLERINTRA can have side effects.

Not all side effects reported for **PLERINTRA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PLERINTRA**, please consult your health care provider for advice.

If any of the of the following happens, stop taking **PLERINTRA** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the ankles or legs, face, lip, tongue, or throat, difficulty in swallowing or breathing'
- 'rash or itching',
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to **PLERINTRA**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina
- changes in the way your heart beats, for example, if you notice it beating faster.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache,
- dizziness
- nausea
- diarrhoea
- fainting
- muscle cramps
- elevated quantity of cholesterol in your blood
- insomnia (difficulty sleeping)
- heart complaints e.g., irregular heartbeat and heart failure
- cough
- constipation
- low blood pressure
- 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
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Less frequent side effects:

- 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

- inflammation of the gallbladder (cholecystitis) – symptoms include severe pain in the right abdomen

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of **PLERINTRA**.

5. How to store PLERINTRA

Store all medicines out of reach of children

Store at or below 25 °C

Store in the original package

Protect from light/ moisture

Do not use after the expiry date stated on the label

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PLERINTRA contains

The active substance is eplerenone

- Lactose monohydrate
- Micro crystalline cellulose
- Sodium Lauryl Sulphate
- Croscarmellose sodium
- Hypromellose
- Talc

Composition of Opadry Yellow YS-1-12524-A

- Hypromellose E464
- Titanium dioxide E171
- Macrogol/PEG E1521
- Polysorbate E433
- Iron oxide yellow E172

What PLERINTRA looks like and contents of the pack

Yellow, film coated, round

30's and 90's Count HDPE Container HDPE Container 60cc with 33 mm neck (H.W) Child Resistant Plastic Caps with Pulp Liners 33 mm

10's White Opaque PVC-Alu Blister pack

Film White opaque PVC width 200mm 250 µ Plain aluminium foil 25 µ (Hard tempered) 196 mm

10's White Opaque PVC-Peel Push Blister pack

Film White opaque PVC width 200mm 250 µ Plain Peel-Push Through foil (50 GSM Paper/12 µ PET/20 µ Aluminium foil/7 GSM HSL) coating on bright side, width 200 mm

500's bulk pack

Poly bags LDPE DMF Clear (9"x12") 92 GSM, Silica Gel Sachet 5 gram, Plain triple laminated bag (13" x 16") (12 Microns PET/ 12 Microns aluminium foil/110 Microns LDPE)

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus

Building No. 2, First floor

74 Waterfall Drive

Applicant/ PHRC: **Hetero Drugs South Africa (Pty) Ltd.**

Product proprietary name: **PLERINTRA 25 mg and 50 mg**

Dosage form and strength: **Each film coated tablet contains 25 mg and 50 mg of eplerenone**

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PLERINTRA 25 mg: 57/6.4/0052

PLERINTRA 50 mg: 57/6.4/0053

Access to the corresponding Professional Information

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