PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

APREPITANT 80 CIPLA (80 mg Capsules)

APREPITANT 125 CIPLA (125 mg Capsules)

APREPITANT COMBI PACK CIPLA (125 mg and 80 mg Capsules)

Aprepitant

Contains sugar:

APREPITANT 80 CIPLA (80 mg capsule) contains 80 mg sucrose

APREPITANT 125 CIPLA (125 mg capsule) contains 125 mg sucrose

Read all of this leaflet carefully before you start taking APREPITANT CIPLA

Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist or other healthcare provider.
- 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 symptoms, talk to your doctor or pharmacist. This includes any possible symptoms not listed in this leaflet.

What is in this leaflet:

1. What is APREPITANT CIPLA and what is used for:
2. What you need to know before you take APREPITANT CIPLA

3. How to take APREPITANT CIPLA
4. Possible side effects
5. How to store APREPITANT CIPLA
6. Contents of the pack and other information.

1. What is APREPITANT CIPLA and what is used for

APREPITANT CIPLA is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy.

2. What you need to know before you use APREPITANT CIPLA

Do not take APREPITANT CIPLA if you:

- are hypersensitive (allergic) to aprepitant or any of the ingredients of APREPITANT CIPLA (as listed in section 6).
- are using other medicines such as pimozide, terfenadine, astemizole, or cisapride
- safety and effectiveness of APREPITANT CIPLA in paediatric patients have not been established.

Warnings and precautions:

Take special care with APREPITANT CIPLA

The presence of other medical conditions may affect the use of APREPITANT CIPLA. Tell your doctor or pharmacist if any of the following applies to you, as you may require special monitoring or a lower dose if you:

- have liver disease because the liver is important in breaking down the medicine in the body. The doctor may therefore have to monitor the condition of your liver
- are taking hormonal contraceptives

If any of these applies to you, tell your doctor or nurse before you take APREPITANT CIPLA

Children and adolescents

APREPITANT CIPLA has not been adequately studied in children. Therefore, APREPITANT CIPLA should not be given to children.

Taking APREPITANT CIPLA with food and drink:

APREPITANT CIPLA can be taken with or without food.

Other medicines and APREPITANT CIPLA

Always tell your health care provider if you are taking any other medicine.
(This includes complementary or traditional medicines.)
Do not take APREPITANT CIPLA with pimozide, terfenadine, astemizole or cisapride. Taking APREPITANT CIPLA with these medications could result in serious or life-threatening problems (see Do not take APREPITANT CIPLA above).

Tell your doctor if you are taking other medicines such as:

- birth control medicines may not work adequately when taken together with APREPITANT CIPLA. Another or additional non-hormonal form of birth control should be used during treatment with APREPITANT CIPLA and for up to 2 months after using APREPITANT CIPLA,
- cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants),
- alfentanil, fentanyl (used to treat pain),
- quinidine (used to treat an irregular heartbeat),
- irinotecan, etoposide, vinorelbine, ifosfamide (medicines used to treat cancer),

- medicines containing ergot alkaloid derivatives such as ergotamine and diergotamine (used for treating migraines),
- warfarin, acenocoumarol (blood thinners; blood tests may be required),
- rifampicin, clarithromycin, telithromycin (antibiotics used to treat infections),
- phenytoin (a medicine used to treat seizures),
- carbamazepine (used to treat depression and epilepsy),
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep),
- ketoconazole (used to treat Cushing's syndrome when the body produces an excess of cortisol),
- itraconazole, voriconazole, posaconazole (antifungals),
- nefazodone (used to treat depression),
- corticosteroids (such as dexamethasone and methylprednisolone),
- anti-anxiety medicines (such as alprazolam),
- tolbutamide (a medicine used to treat diabetes).

Pregnancy and breastfeeding

This medicine should not be used during pregnancy or breastfeeding. If you are pregnant, planning to have a baby or breastfeeding, ask the doctor for advice before taking APREPITANT CIPLA. It is not known whether APREPITANT CIPLA is excreted in human milk. It is important to tell the doctor or healthcare provider if you are breastfeeding or are planning to breastfeed before taking APREPITANT CIPLA.

Driving and using machines

It should be considered that some people feel dizzy and sleepy after taking APREPITANT CIPLA. If you feel dizzy or sleepy, avoid driving or using machines or tools after taking APREPITANT CIPLA.

APREPITANT CIPLA contains a sugar in the form of sucrose

If you have been told by your health care provider that you have an intolerance to some sugars contact your health care provider before taking APREPITANT CIPLA. APREPITANT CIPLA contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

APREPITANT CIPLA contains sodium

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

3. How to take APREPITANT CIPLA

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

Always take APREPITANT CIPLA exactly as your doctor or healthcare provider has told you. Check with your doctor or healthcare provider if you are not sure.

The recommended dose of APREPITANT CIPLA is

125 mg orally 1 hour prior to chemotherapy treatment (Day 1) and 80 mg once daily in the morning on Days 2 and 3.

Duration of the therapy

Your doctor will tell you how long your treatment with APREPITANT CIPLA will last. Do not stop treatment early.

If you have the impression that the effect of APREPITANT CIPLA is too strong or too weak, talk to your doctor or pharmacist.

Method of administration

For oral administration.

The capsules should be swallowed whole with water.

You can take APREPITANT CIPLA with or without food.

If you take more APREPITANT CIPLA than you should.

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

4. Possible side effects

APREPITANT CIPLA can have side effects.

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

If any of the following happens, stop taking / using APREPITANT CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause 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 APREPITANT CIPLA You may need urgent medical attention or hospitalisation.

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

- Palpitations,
- Fever.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following frequent side effects:

- Decreased appetite
- Headache
- Hiccups
- Indigestion
- Feeling tired
- abnormal blood liver tests

Tell your doctor if you notice any of the following less frequent side-effects:

- infections,
- anaemia (lack of blood),
- feeling thirsty,
- anxiety,
- feeling happy or confused,
- dizziness,
- feeling tired,
- mental health disorders,
- change in taste,
- pink eye,
- ringing in the ears,

- slow heart rate and heart problems,
- hot flushes,
- persistent sore throat, sneezing, cough, post-nasal drip, throat infection,
- burping, nausea, acid reflux, vomiting, stomach pain, dry mouth, gas,
- hard faeces,
- acne,
- muscle spasm, muscle weakness,
- painful urination,
- abnormal frequent urination,
- decreased weight,
- decreased sodium blood and neutrophil test,
- glucose in urine,
- sensitivity to light.

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 or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. Alternatively, you can also contact Cipla by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).
By reporting side effects, you can help provide more information on the safety of APREPITANT CIPLA.

5. How to store APREPITANT CIPLA

Store at or below 25 °C

KEEP OUT OF REACH OF CHILDREN

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 APREPITANT CIPLA contains

The active substance is aprepitant.

Each APREPITANT 80 CIPLA (80 mg capsule) contains 80 mg aprepitant.

Each APREPITANT 125 CIPLA (125 mg capsule) contains 125 mg aprepitant.

Each APREPITANT COMBI PACK CIPLA (80 mg and 125 mg capsule) contains aprepitant 80 mg and aprepitant 125

mg capsules

APREPITANT CIPLA contains sugar in the form of sucrose:

APREPITANT 80 CIPLA (80 mg capsule) contains 80 mg sucrose

APREPITANT 125 CIPLA (125 mg capsule) contains 125 mg sucrose

The other ingredients are hypromellose 2910, poloxamer 407, microcrystalline cellulose, gelatin, sodium lauryl sulfate, titanium dioxide E171, shellac, iron oxide black, propylene glycol

What APREPITANT CIPLA looks like and contents of the pack

APREPITANT 80 CIPLA (80 mg capsules): Opaque hard gelatin capsules with a white cap and white body, printed with “80 mg” on the body.

APREPITANT 125 CIPLA (125 mg hard capsules): Opaque hard gelatin capsules with a 24 pink cap and white body, printed with “125 mg” on the body.

APREPITANT 80 CIPLA (80 mg capsules) are packed in a cardboard box containing OPA/ALU/PVC

450 -Aluminium foil blisters containing 5 capsules.

APREPITANT 125 CIPLA (125 mg hard capsules) are packed in a cardboard box containing OPA/ALU/PVC-Aluminium foil blisters containing 5 capsules.

APREPITANT COMBI PACK CIPLA (80 and 125 mg capsules) are packed in a cardboard box containing OPA/ALU/PVC -Aluminium foil blisters containing one 125 mg capsule and two 80 mg capsules.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

This leaflet was last revised in

14 April 2022

Registration number

52/5.7.2/0578