Applicant/PHCR: DR REDDY'S LABORATORIES (PTY) LTD
Product proprietary name: NAUSAP 150 IV
Dosage form: Lyophilised powder for solution for infusion
Strength: Each vial contains 245,3 mg of fosaprepitant dimeglumine equivalent to 150 mg fosaprepitant free acid

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NAUSAP 150 IV, 150 mg, Lyophilised Powder for Solution for Infusion

Fosaprepitant

Contains sugar (lactose anhydrous)

Each vial contains 375 mg of lactose anhydrous

Read all of this leaflet carefully before you are given NAUSAP 150 IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What NAUSAP 150 IV is and what it is used for

NAUSAP 150 IV contains the active substance fosaprepitant which is converted to aprepitant in your body.

NAUSAP 150 IV belongs to a group of medicines called "neurokinin 1 (NK_1) receptor antagonists".

NAUSAP 150 IV is used in combination with other medicines to prevent and control nausea

(feeling sick) and vomiting caused by your chemotherapy (cancer treatment).

2. What you need to know before you use NAUSAP 150 IV

NAUSAP 150 IV should not be administered to you

- if you are hypersensitive (allergic) to fosaprepitant, aprepitant or to polysorbate 80 or any of the other ingredients of NAUSAP 150 IV (listed in section 6)
- with medicines containing pimozide (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions), cisapride (used for treating digestive problems). Tell your doctor if you are taking these medicines since your treatment must be modified before you start using NAUSAP 150 IV.
- if you are pregnant or breastfeeding.

Do not give NAUSAP 150 IV to children, because NAUSAP 150 IV has not been adequately studied in children.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using NAUSAP 150 IV:

- if you have or have had any past or present medical problems
- if you have liver disease. Before treatment with this medicine, tell your doctor if you have liver disease because your liver is important in breaking down the medicine in your body. Your doctor may therefore have to monitor the condition of your liver.
- If you have any allergies
- If you are taking or plan to take any medicine, even those you can get without a prescription or herbal products

Tell your doctor or nurse if you experience local irritation at the injection site.

Children and adolescents

NAUSAP 150 IV has not been adequately studied in children. Therefore, NAUSAP 150 IV should not be given to children

Use in elderly

No dosage adjustment is necessary for elderly patients.

Other medicines and NAUSAP 150 IV

Always tell your healthcare provider if you are taking any other medicine.

(This includes complementary or traditional medicines.)

NAUSAP 150 IV can affect other medicines both during and after treatment with NAUSAP 150 IV.

Do not take NAUSAP 150 IV with pimozide, terfenadine, astemizole or cisapride.

Taking NAUSAP 150 IV with these medicines could result in **serious or life-threatening problems** (see also **"**NAUSAP 150 IV should not be administered to you").

There are some medicines that require a dose adjustment if taken with NAUSAP 150 IV.

The effects of NAUSAP 150 IV or other medicines might be influenced if you take NAUSAP 150 IV together with other medicines including those listed below.

Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- birth control medicines which can include birth control pills, skin patches, implants, and certain Intrauterine devices (IUDs) that release hormones may not work adequately when taken together with NAUSAP 150 IV. Another or additional non-hormonal form of birth control should be used during treatment with NAUSAP 150 IV and for up to 1 month after using NAUSAP 150 IV
- cyclosporine, tacrolimus, sirolimus, everolimus (immunosuppressants)
- alfentanil, fentanyl (used to treat pain)
- quinidine (used to treat an irregular heart beat)
- irinotecan, etoposide, vinorelbine, ifosfamide, docetaxel, cyclophosphamide, paclitaxel (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, troleandomycin (antibiotics used to treat infections)
- phenytoin (a medicine used to treat seizures)

- carbamazepine (a medicine used to treat depression and epilepsy)
- midazolam, triazolam, phenobarbital (medicines used to produce calmness or help you sleep)
- St. John's Wort (a herbal preparation used to treat depression)
- ritonavir, nelfinavir (used to treat HIV infections)
- ketoconazole except shampoo (an antifungal; also used to treat Cushing's syndrome – when the body produces an excess of cortisol)
- itraconazole, voriconazole, posaconazole (antifungals)
- nefazodone, paroxetine (used to treat depression)
- diltiazem (a medicine used to treat high blood pressure)
- corticosteroids (such as dexamethasone and methylprednisolone)
- anti-anxiety medicines (such as alprazolam)
- tolbutamide (a medicine used to treat diabetes)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

For information regarding birth control, see "Other medicines and NAUSAP 150 IV".

NAUSAP 150 IV must not be given to women who are pregnant or who are breastfeeding their babies.

It is not known whether NAUSAP 150 IV is excreted in human milk.

Driving and using machines

There have been side effects reported with NAUSAP 150 IV that may affect your ability to drive or operate machinery. Dizziness, fatigue and sleepiness may occur after using NAUSAP 150 IV. If you get dizzy, tired or sleepy, avoid driving or using machines after using this medicine (see "Possible side effects").

Even though individual responses to NAUSAP 150 IV may vary, caution is required when driving a car or operating machines (see **"**Possible side effects").

3. How NAUSAP 150 IV is given

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

You will not be expected to give yourself NAUSAP 150 IV. It will be given to you by a person who is qualified to do so.

In adults, the recommended dose of NAUSAP 150 IV is 150 mg fosaprepitant on Day 1 (day of chemotherapy).

The powder is reconstituted and diluted before use. The solution for infusion is given to you by a healthcare professional, such as a doctor or nurse, via an intravenous infusion (a drip) over 20 to 30 minutes approximately 30 minutes before your start of chemotherapy treatment. Your doctor will ask you to take other medicines including a corticosteroid (such as dexamethasone) and a "5-HT_3 antagonist" (such as ondansetron) for preventing nausea and vomiting. Check with your doctor or pharmacist if you are not sure.

If you receive more NAUSAP 150 IV than you should

Since a health care provider will administer NAUSAP 150 IV, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you miss a dose of NAUSAP 150 IV

If you are concerned that you may have missed a dose of NAUSAP 150 IV, talk to your doctor, pharmacist or nurse straight away.

Since a health care provider will administer NAUSAP 150 IV, it is unlikely that the dose will be missed.

4. Possible side effects

NAUSAP 150 IV can have side effects.

Not all side effects reported for NAUSAP 150 IV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving NAUSAP 150 IV, please consult your health care provider for advice.

If any of the following happens, stop using NAUSAP 150 IV and tell your doctor

immediately:

- Hives (raised itchy/bumps on the skin), rash, itching, redness of the face/skin, swelling of the face, throat, tongue and lips, difficulty breathing or swallowing, or a serious decrease of blood pressure (frequency not known, cannot be estimated from the available data). These are signs of a serious allergic reaction.
- Infusion site reactions (ISR) at or near the infusion site. Most severe ISR have happened with a certain type of chemotherapy medicine that can burn or blister your skin (vesicant) with side effects, including pain, swelling and redness. Death of skin tissue (necrosis) has happened in some people getting this type of chemotherapy medicine.

These are all very serious side effects. You need immediate/urgent medical attention.

Other side effects that have been reported are listed below.

Tell your doctor or nurse if you notice any of the following:

Frequent side effects:

- constipation, indigestion
- headache
- fatigue
- loss of appetite
- hiccups
- increased amount of a liver enzyme (ALT) in your blood.

Less frequent side effects:

- bacterial infection, fungal infection
- fever with increased risk of infection, lowering of red blood cells
- excessive thirst
- anxiousness, disorientation, euphoria (feeling of extreme happiness)
- dizziness, sleepiness, difficulty thinking, lack of energy, taste disturbance
- eye discharge and itching

- ringing in the ear
- slow heartbeat, heart and blood vessel disease
- fast or irregular heartbeats, blood pressure increased
- hot flush, reddening of the face/skin
- cough, mucus in back of throat, throat irritation, sneezing, sore throat
- burping, nausea, vomiting, heartburn, abdominal pain, dry mouth, passing wind, hard stools, perforated duodenal ulcer (an ulcer in the first part of the small intestine), sores in mouth, bloating, inflammation of the small intestine and colon
- rash, acne, sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin, itching rash, Stevens-Johnson syndrome/toxic epidermal necrolysis (severe skin reaction)
- muscle spasms, muscle weakness
- painful or burning urination, frequent urination, passing more urine than normal, presence of sugar or blood in urine
- weakness, generally feeling unwell, swelling, chest discomfort, change in the manner of walking
- increased liver enzymes (AST, ALP), lowering of white blood cells, low sodium levels in the blood, weight loss
- infusion site redness, infusion site itching, infusion site pain, hardening of site of infusion, infusion site vein inflammation related to a blood clot.

<u>Frequency not known:</u>

- difficulty with speech, upper abdominal pain, shortness of breath, reduced sense of touch, difficulty sleeping, stomach discomfort, eye problems, wheezing, inactivity of the bowel, abnormal bowel sounds, disorders of the special senses, itching, hives.

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of NAUSAP 150 IV.

5. How to store NAUSAP 150 IV

NAUSAP 150 IV should be stored refrigerated at 2 to 8 °C.

Since NAUSAP 150 IV does not contain a preservative it is advisable that the product be used immediately after reconstitution.

The reconstituted and diluted solution is stable for 24 hours at or below 25°C.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What NAUSAP 150 IV contains

- The active substance is fosaprepitant. Each vial contains 245,3 mg of fosaprepitant dimeglumine equivalent to 150 mg fosaprepitant free acid as sterile, lyophilised powder.
- The other ingredients are edetate disodium anhydrous, lactose anhydrous and polysorbate 80.

What NAUSAP 150 IV looks like and contents of the pack

NAUSAP 150 IV is a white to off-white lyophilised cake or powder for solution for infusion.

It is mixed with a solvent to form a liquid before it is administered.

When reconstituted: A clear, pale yellow coloured solution with no visible particles.

The powder is contained in a clear glass vial with a grey rubber stopper and an aluminium seal with a red plastic flip off cap.

Each vial contains 150 mg of fosaprepitant.

Pack sizes: 1's.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd.

website: http://www.drreddys.co.za

For any information about this medicine, please contact the local representative of the Holder of

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