

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VOPREP 80 hard capsules
VOPREP 125 hard capsules
VOPREP Combi Pack hard capsules

Aprepitant

Contains sugar:

Each 80 mg capsule contains 80 mg sucrose.

Each 125 mg capsule contains 125 mg sucrose.

Read all of this leaflet carefully before you start taking VOPREP.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **VOPREP** 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 VOPREP is and what it is used for
2. What you need to know before you use VOPREP
3. How to use VOPREP
4. Possible side effects
5. How to store VOPREP
6. Contents of the pack and other information

1. What VOPREP is and what it is used for

VOPREP is a member of a class of medicines called neurokinin 1 receptor antagonists.

VOPREP is used along with other medicines to prevent and control nausea (feeling sick) and vomiting (throwing up) caused by your cancer chemotherapy treatment.

2. What you need to know before you use VOPREP

Do not take VOPREP

- if you are hypersensitive (allergic) to aprepitant or any of the other ingredients of VOPREP (see section 6).
- with medicines containing pimozone (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions), cisapride (used for treating digestive problems). Tell the doctor if you are taking these medicines since the treatment must be modified before you start taking VOPREP.

Warnings and precautions

Take special care with VOPREP:

- If you are taking or plan to take any medication. (**See Do not take VOPREP and Other medicines and VOPREP**).
- If you have a liver disease.

Children and adolescents

VOPREP has not been studied in children under the age of 18 years. Therefore VOPREP should not be given to children.

Other medicines and VOPREP

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

Do not take VOPREP with pimozone (used to treat psychiatric illnesses), terfenadine and astemizole (used for hay fever and other allergic conditions), cisapride (used for treating digestive problems) (see **Do not take VOPREP**). Taking VOPREP with these medicines could result in serious or life-threatening problems.

The effects of VOPREP or other medicines might be influenced if you take VOPREP with other medicines.

Tell your doctor or pharmacist if you are currently taking:

- Birth control medicines which can include birth control pills, skin patches, implants and intrauterine devices (IUDs). Your doctor may advise you to use an additional non-hormonal form of birth control during treatment with VOPREP and for up to 2 months after using VOPREP.
- Ciclosporin, tacrolimus, sirolimus, everolimus (immunosuppressants).
- Alfentanil, fentanyl (used to treat pain).
- Quinidine (used to treat an irregular heartbeat).
- 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 (antibiotics used to treat infections).
- Phenytoin (a medicine used to treat seizures).
- Carbamazepine (used to treat depression and epilepsy).
- Midazolam, triazolam, phenobarbitone (medicines used to produce calmness or help you sleep).
- St John's Wort (a herbal preparation used to treat depression).
- Protease inhibitors (used to treat HIV infections).
- Ketoconazole (used to treat Cushing's syndrome - when the body produces an excess of cortisol).
- Itraconazole, voriconazole, posaconazole (antifungals).
- Nefazodone, paroxetine (used to treat depression).
- Corticosteroids (such as dexamethasone and methylprednisolone).
- Anti-anxiety medicines (such as alprazolam).
- Tolbutamide (a medicine used to treat diabetes).

VOPREP with food and drink

For oral use VOPREP can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking VOPREP.

VOPREP is not recommended during pregnancy and breastfeeding.

It is not known whether VOPREP is excreted in human milk; therefore, breastfeeding is not recommended during treatment with VOPREP.

Driving and using machines

It should be taken into account that some people may feel dizzy and sleepy after taking VOPREP. If you feel dizzy or sleepy you should avoid driving or using machines after taking VOPREP.

VOPREP contains sucrose

VOPREP contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact the doctor before taking VOPREP.

3. How to use VOPREP

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

Always take VOPREP exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one VOPREP 125 capsule 1 hour before you start your chemotherapy treatment and one VOPREP 80 capsule each morning for the 2 days following your chemotherapy treatment.

Swallow the capsule whole with some liquid.

Your doctor will prescribe VOPREP together with other medicines, including a corticosteroid (such as dexamethasone) and a 5HT₃ antagonist (such as ondansetron) to prevent nausea and vomiting.

Your doctor will tell you how long your treatment with VOPREP will last. Do not stop treatment early. If you have the impression that the effect of VOPREP is too strong or too weak, tell your doctor or pharmacist.

If you take more VOPREP than you should

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

Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have taken.

If you forget to take VOPREP

If you miss a dose, contact your doctor for advice and further instructions.

4. Possible side effects

VOPREP can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to VOPREP. 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:

Less frequent:

- Fast or irregular heartbeat.
- Slow heartbeat, heart and blood vessel disease.
- Extremely serious allergic skin reaction, with blistering of the skin, mouth, eyes and genitals.
- Bacterial or fungal infections.
- Frequent urination, passing more urine than normal.

- Stomach ulcer perforation, inflammation of the small intestine and colon (causing symptoms such as abdominal cramps, pain and tenderness, blood in stool, loss of appetite and fever).

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Decreased appetite.
- Headache.
- Hiccups.
- Constipation, indigestion.
- Tiredness.

Less frequent:

- Dizziness, sleepiness.
- Feeling anxious.
- Acne.
- Burping, nausea, vomiting, heartburn, stomach pain, dry mouth, passing wind.
- Severe constipation, sores in your mouth, bloating.
- Weakness, generally feeling unwell, lack of energy.
- Hot flushes, reddening of your face or skin.
- Sensitivity of the skin to sun, excessive sweating, oily skin, sore on the skin.
- Chest discomfort, swelling, coughing, mucus in the back of your throat, throat irritation, sneezing, sore throat.
- Eye discharge and itching.
- Ringing in the ear.
- Muscle spasms, muscle weakness.
- Weight loss.

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

Reporting of side effects

If you experience 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 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 VOPREP.

5. How to store VOPREP

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Do not remove the capsules from blister strips until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VOPREP contains

The active substance is aprepitant.

Each 80 mg capsule contains 80 mg aprepitant.

Each 125 mg capsule contains 125 mg aprepitant.

The other ingredients are hypromellose, microcrystalline cellulose, poloxamer, sucrose, gelatin, sodium laurilsulfate, titanium dioxide (E171), black iron oxide (E172), propylene glycol (E1520), shellac. The 125 mg capsules also contain iron oxide red (E172).

What VOPREP looks like and contents of the pack

The 80 mg capsules are opaque hard gelatine capsule with a white cap and white body printed with ‘80mg’ on the body.

The 125 mg capsules are opaque hard gelatine capsule with a pink cap and white body, printed with ‘125mg’ on the body.

The capsules are supplied in aluminium/aluminium blister strips in an outer carton.

Pack sizes: 5 or 10 capsules.

Not all pack sizes may be marketed.

Holder of certificate of registration:

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South Africa

Tel. nr: 011 635 0000

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