Applicant : Eurolab (Pty) Ltd
Proprietary name : Aprepitant Eurolab, 80 mg & 125 mg & Combi pack
Dosage form and strength : Hard capsules, 80 mg & 125 mg
Date of submission : 12 May 2020
Approval date : 29 September 2020

APPROVED PATIENT INFORMATION LEAFLET FOR APREPITANT EUROLAB

SCHEDULING STATUS:

S4

APREPITANT 80 EUROLAB

APREPITANT 125 EUROLAB

APREPITANT COMBI PACK EUROLAB

Hard capsules

Active substance: Aprepitant

APREPITANT EUROLAB contains sugar in the form of sucrose.

The 80 mg capsule contains 80 mg of sucrose.

The 125 mg capsule contains 125 mg of sucrose.

***Read all of this leaflet carefully before you start taking* APREPITANT EUROLAB**

- *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.*
- **APREPITANT EUROLAB** *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 **APREPITANT EUROLAB** is and what it is used for

2. What you need to know before you take **APREPITANT EUROLAB**

3. How to take **APREPITANT EUROLAB**

4. Possible side effects

5. How to store **APREPITANT EUROLAB**

6. Contents of the pack and other information

1. What APREPITANT EUROLAB is and what it is used for

APREPITANT EUROLAB belongs to a group of medicines called neurokin 1 (NK1) receptor antagonists that helps alongside other medicines to prevent and control nausea (feeling sick in your throat and stomach) and vomiting (throwing up) caused by your cancer treatment.

APREPITANT EUROLAB in combination with other anti-emetic medicines, is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of:

- highly emetogenic cancer chemotherapy
- Moderately emetogenic cancer chemotherapy

2. What you need to know before you take APREPITANT EUROLAB

Do not take APREPITANT EUROLAB:

- **APREPITANT EUROLAB** is contraindicated in patients with a known hypersensitivity to aprepitant or to any of the ingredients of **APREPITANT EUROLAB**
- **APREPITANT EUROLAB** should not be used concurrently with pimozide, astemizole or cisapride. Inhibition of cytochrome P450 isoenzyme 3A4 (CYP3A4) by aprepitant could result in elevated plasma concentrations of these agents, potentially causing serious or life-threatening reactions.
- Safety and efficacy in paediatric patients have not been established.

Warnings and precautions

- Tell the doctor or health care provider before taking **APREPITANT EUROLAB**

Take special care:

- if you are taking other medicine such as medicine to treat fungal infections (e.g. ketoconazole, itraconazole), medicine to treat depression (e.g. nefazodone, paroxetine), medicine to treat bacterial infections (e.g. troleandomycin, clarithromycin) or medicine to treat viral infections like HIV/AIDS (e.g. ritonavir, nelfinavir).
- if you are taking blood thinning medicine such as warfarin.
- if you are taking hormonal contraceptives. You will need to use alternative or backup methods of contraception for 1 month following the last dose of **APREPITANT EUROLAB**.
- if you have or did have a liver disease, since **APREPITANT EUROLAB** gets broken down by the liver. Your liver may have to be monitored while taking **APREPITANT EUROLAB**.

Children and Adolescents

Do not give **APREPITANT EUROLAB** 80 mg and 125 mg capsules to children because **APREPITANT EUROLAB** has not been studied in this population.

Other medicines and APREPITANT EUROLAB

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

APREPITANT EUROLAB can affect other medicines, both during and after treatment with it. There are some medicines that should not be taken with **APREPITANT EUROLAB** (such as medicines containing pimozide, astemizole, and cisapride) or that require a dose adjustment (see also 'Do not take **APREPITANT EUROLAB**).

The effects of aprepitant or other medicines might be influenced if you take aprepitant

together with other medicines including those listed below. Please talk to the doctor or pharmacist if you take 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 **APREPITANT EUROLAB**. Another or additional non-hormonal form of birth control should be used during treatment with **APREPITANT EUROLAB** and up to 1 month after taking **APREPITANT EUROLAB**.

- 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)
- St. John's Wort (a herbal preparation used to treat depression)
- protease inhibitors (used to treat HIV infections)
- ketoconazole, except shampoo (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)

APREPITANT EUROLAB with food and drink

Swallow **APREPITANT EUROLAB** capsule whole with some liquid. **APREPITANT EUROLAB** can be taken with or without food.

Pregnancy, breastfeeding and fertility

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 taking this medicine.

It is not known if **APREPITANT EUROLAB** is excreted in human milk; therefore breastfeeding is not recommended during treatment with **APREPITANT EUROLAB**.

Women of childbearing potential / Contraception in males and females

The efficacy of hormonal contraceptives may be reduced during and for 28 days after administration of **APREPITANT EUROLAB**.

Alternative non-hormonal back-up methods of contraception should be used during treatment with **APREPITANT EUROLAB** and for 1 month following the last dose of **APREPITANT EUROLAB**.

Fertility

The potential for effects of **APREPITANT EUROLAB** on fertility has not been fully characterised because exposure levels above the therapeutic exposure in humans could not be attained in animals.

Driving and using machines

It is not always possible to predict to what extent **APREPITANT EUROLAB** 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 **APREPITANT EUROLAB** affects them.

You may feel dizzy while taking this medicine. If this happens, do not drive or use any tools or machines until you are feeling well again.

3. How to take APREPITANT EUROLAB

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

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

Always take **APREPITANT EUROLAB** together with other medicines prescribed to prevent nausea and vomiting.

The usual dose is:

Day 1: One **APREPITANT 125 EUROLAB** capsule 1 hour before you start chemotherapy and Day 2 and 3: One **APREPITANT 80 EUROLAB** capsule each day in the morning.

You can take **APREPITANT EUROLAB** WITH OR WITHOUT FOOD. Swallow the capsule whole with some liquid.

If you take more APREPITANT EUROLAB 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 forget to take APREPITANT EUROLAB

If you have missed a dose, contact your doctor or pharmacist for advice.

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

If you stop taking APREPITANT EUROLAB

Your doctor will tell you how long your treatment with **APREPITANT EUROLAB** will last. Do not stop treatment early without consulting your doctor because it may decrease the effectiveness of the treatment.

4. Possible side effects

APREPITANT EUROLAB can have side effects.

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

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

Hives, rash, itching, difficulty breathing or swallowing (frequency not known); these are signs of an allergic reaction. If you have them, you may have had a serious reaction to **APREPITANT EUROLAB**. You may need urgent medical attention.

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

Frequent side effects:

- constipation, indigestion
- headache
- tiredness
- loss of appetite

- hiccups
- increase amount of liver enzymes in your blood

Less frequent side effects:

- dizziness, sleepiness
- acne, rash
- anxiousness
- burping, nausea, vomiting, heartburn, stomach pain, dry mouth
- passing wind
- increased painful or burning urination
- weakness, generally feeling unwell
- hot flush/ reddening of the face or skin
- fast or irregular heartbeats
- fever with increased risk of infection, lowering of red blood cells
- difficulty thinking, lack of energy, taste disturbance
- sensitivity of the skin to sun, excessive sweating, oily skin, sores on skin
- itching rash, Stevens-Johnson syndrome / toxic epidermal necrolysis (rare)
- severe skin reaction
- euphoria (feeling of extreme happiness), disorientation
- bacterial infection, fungal infection
- chest discomfort, swelling, change in the manner of walking
- cough, mucus in back of throat, throat irritation sneezing, sore throat
- eye discharge and itching
- ringing in the ear
- spasms, muscle weakness

- excessive thirst
- slow heartbeat, heart and blood vessel disease
- lowering of white blood cells, low sodium levels in the blood, 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 get side effects, talk to your doctor or pharmacist. 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 **APREPITANT EUROLAB**. You should also report side effects to the Holder of Certificate of Registration, (HCR),

Eurolab (Pty) Ltd.

Contact details of the HCR:

Email: info@eurolab.co.za

Tel. no.: +27 (0)11 656 0031

24-Hour Tel no.: 082 389 9048

5. How to store APREPITANT EUROLAB

- *S*tore all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original container package in order to protect from moisture.
- Keep blisters in the carton until required for use.
- Do not use after the expiry date printed on the label or carton.

- 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 EUROLAB contains

The active substance is aprepitant

APREPITANT EUROLAB is available as:

APREPITANT 80 EUROLAB: Each hard capsule contains 80 mg aprepitant

APREPITANT 80 EUROLAB: Each hard capsule contains 125 mg aprepitant

The other ingredients are sucrose; microcrystalline sphere 500 (E460); hydroxypropylcellulose (E463), sodium laurisulfate, gelatin, titanium dioxide (E171), iron oxide red (E172).

What APREPITANT EUROLAB looks like and contents of the pack

APREPITANT 80 EUROLAB: Opaque size 2 hard gelatin capsules with a white body and cap containing white to off white pellets

APREPITANT 80 EUROLAB: Opaque size 1 hard gelatin capsules with a white body and pink cap containing white to off-white pellets.

APREPITANT 80 EUROLAB and **APREPITANT 125 EUROLAB** hard capsules are packed in a carton containing 5 individually packaged in single ALU-OPA/ALU/PVC foil blisters. Each carton contains 5 blisters.

APREPITANT COMBI PACK EUROLAB are packaged in a carton containing individually packaged in single Alu-OPA/Alu/PVC foil blister packs as a combination containing one 125 mg capsule and two 80 mg capsules in a carton.

Holder of Certificate of Registration

Eurolab (Pty) Ltd.

Woodmead Office Park

3 Stirrup Lane

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Woodmead, 2144

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Registration numbers

APREPITANT 80 EUROLAB:	A53/5.7.2/0234	
	Namibia Reg No.:	NS2 21/5.7.2/0034
	Tanzania Reg No.:	TAN 21 HM 0337
APREPITANT 125 EUROLAB:	A53/5.7.2/0235	
	Namibia Reg No.:	NS2 21/5.7.2/0035
	Tanzania Reg No.:	TAN 21 HM 0336
APREPITANT COMBI PACK EUROLAB:	A53/5.7.2/0236	
	Namibia Reg No.:	NS2 21/5.7.2/0036
	Tanzania Reg No.:	TAN 21 HM 0335