SCHEDULING STATUS

S2

AVARINEX SYRUP

2.5 mg/5 mL Desloratadine, syrup.

Contains sugar: sucrose 2.5 mg

Contains sorbitol: 1400 mg

Contains propylene glycol: 500 mg

Contains preservative: Sodium benzoate 5 mg

Read all of this leaflet carefully before you start taking AVARINEX SYRUP.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- **AVARINEX SYRUP** has been prescribed for you personally or your child 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 **AVARINEX SYRUP** is and what it is used for

2. What you need to know before you take **AVARINEX SYRUP**

3. How to take **AVARINEX SYRUP**

4. Possible side effects

5 How to store **AVARINEX SYRUP**

6. Contents of the pack and other information

1. What AVARINEX SYRUP is and what it is used for:

The active substance is Desloratadine 2,5 mg per 5 ml syrup. **AVARINEX SYRUP** is an anti-allergy medicine. It helps control your or your child's allergic reaction and its symptoms.

AVARINEX SYRUP relieves symptoms associated with allergic rhinitis (e.g. hay fever), such as sneezing, runny or itchy nose and burning or itchy eyes.

AVARINEX SYRUP may also be used to relieve the symptoms associated with chronic idiopathic urticaria (itching, redness and number and size of hives).

What you need to know before you take AVARINEX SYRUP:

Do not take AVARINEX SYRUP:

- If you or your child is hypersensitive (allergic) to desloratadine or to any of the other ingredients of **AVARINEX SYRUP** (see section 6 "What this product contains").
- Do not give **AVARINEX SYRUP** to your child if he/she is under two years of age.
- If you are pregnant or breastfeeding.
- If you or your child suffers from a disease called porphyria (a group of disorders that can cause nerve or skin problems).
- If you or your child are allergic to other antihistamines (check with your doctor if you are unsure).
- If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

Talk to your doctor or pharmacist before taking AVARINEX SYRUP:

Take special care with AVARINEX SYRUP if you or your child:

- have liver or kidney problems.
- have a medical or family history of seizures
- have any other medical conditions.
- Are going to have a skin test for allergies done, **AVARINEX SYRUP** should not be consumed 48 hours before you do the test.

Other medicines and AVARINEX SYRUP:

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

Before you take AVARINEX SYRUP, make sure your doctor knows if you or your child are taking the following medicines:

- ketoconazole: an antifungal medicine used to treat certain kinds of fungal or yeast infections.
- erythromycin: an antibiotic medicine used to treat certain kinds of bacterial infections and often used for people who have an allergy to penicillins.
- azithromycin: an antibiotic medicine to treat certain kinds of bacterial infections (such as pneumonia and ear infections).
- antihistamines: a medicine commonly used to treat allergies.
- fluoxetine: a medicine used to treat depression.
- cimetidine: a medicine used treat stomach ulcers, acid reflux, or to prevent and treat symptoms of heartburn associated with acid, indigestion and sour stomach.

AVARINEX SYRUP with food, drink, and alcohol:

AVARINEX SYRUP may be taken with or without food.

Pregnancy and breastfeeding and fertility:

You should not use **AVARINEX SYRUP** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine**.**

Driving and using machines:

Some people may experience sedation and if you do, you should not drive or perform complicated tasks.

AVARINEX SYRUP contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

AVARINEX SYRUP contains sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

AVARINEX SYRUP contains propylene glycol

This medicine contains 500 mg propylene glycol in each 5 mL which is equivalent to 20-25 mg/kg body weight.

2. How to take AVARINEX SYRUP:

Always take **AVARINEX SYRUP** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

Children 2 to 5 years of age:

2.5 ml (1.25 mg) (1/2 a medicine measure) once a day,

Children 6 to 11 years of age:

5 ml (2.5 mg) (1 medicine measure) once a day,

Adults and adolescents (12 years of age and over):

10 ml (5 mg) (2 medicine measures) once a dav.

Your doctor will determine the duration of your treatment. **AVARINEX SYRUP** should not be taken for longer than 4 weeks.

Method of administration

For oral use only. To be taken with or without meals.

If you take more AVARINEX SYRUP than you should:

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

If you forget to take a dose of AVARINEX SYRUP:

Try to take/give **AVARINEX SYRUP** as prescribed by your healthcare professional. However, if you or your child miss a dose, do not take/give a double dose to make up for forgotten individual doses.

3. Possible side effects

AVARINEX SYRUP can have side effects.

Not all side-effects reported for this medicine are included in this leaflet. Should your or your child’s general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Allergic reaction: if you or your child develop skin rash/ burning or prickling sensation, or fever.

These are all very serious side effects. If you or your child have them, you or your child may have had a serious reaction to **AVARINEX SYRUP**. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent:

- Headache
- Trouble sleeping (insomnia)
- Diarrhoea
- Dry mouth
- Tiredness (fatigue)
- Fever

Less Frequent:

- Hallucinations
- Dizziness
- Convulsions (seizures)
- Drowsiness
- Rapid heartbeat
- Palpitations (unpleasant sensation of irregular and/or forceful beating of the heart).

- Stomach pain
- Nausea
- Vomiting
- Indigestion
- Sensitivity to light
- Muscle pain
- Abnormal liver function tests
- Liver inflammation

Frequency Unknown:

- Increased appetite
- Aggression
- Jaundice (yellow colouration of skin)
- Physical weakness
- Weight gain

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

Reporting of side effects

If you get side effects, talk to your doctor or 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 **AVARINEX SYRUP**.

4. **How to store AVARINEX SYRUP**

- **STORE ALL MEDICINE OUT OF REACH OF CHILDREN**

- Store **AVARINEX SYRUP** at or below 30 °C in the original container.
- Do not use this medicine after the expiry date shown on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

5. Contents of the pack and other information

What AVARINEX SYRUP contains:

The active substance is desloratadine

The other ingredients are: Beta cyclodextrin, citric acid anhydrous, disodium EDTA, glycerin, orange flavour, polyvinyl pyrrolidone, propylene glycol, sodium benzoate, sodium citrate, sorbitol solution, sucralose, sunset yellow.

What AVARINEX SYRUP looks like and contents of the pack

AVARINEX SYRUP:

Orange coloured, clear liquid having an orange flavour.

Contents of the pack

AVARINEX syrup:

Is packaged in a 60 mL or 100 mL or 150 mL PET bottle, with a PP cap in an outer carton with package insert.

Holder of Certificate of Registration

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Access to the corresponding Professional information.

Follow the link for the corresponding Professional Information for Avarinex:

pi-pil-repository.innovata.co.za,

Alternatively, please scan the QR code below:

