PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

SEASONEZE 10 mg film-coated tablets

Cetirizine

Contains sugar (66,4 mg lactose monohydrate per tablet).

Read all of this leaflet carefully because it contains important information for you

- SEASONEZE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take SEASONEZE carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share SEASONEZE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What SEASONEZE is and what it is used for
2. What you need to know before you take SEASONEZE
3. How to take SEASONEZE
4. Possible side effects
5. How to store SEASONEZE
6. Contents of the pack and other information

1. What SEASONEZE is and what it is used for

SEASONEZE contains the active ingredient cetirizine dihydrochloride, which belongs to a group of medicines called antihistamines.

SEASONEZE is used to treat hayfever, rhinitis (runny nose) and urticaria (itchy rash or hives).

2. What you need to know before you take SEASONEZE

Do not take SEASONEZE if:

- You are hypersensitive (allergic) to cetirizine, hydroxyzine or any of the other ingredients of SEASONEZE (listed in section 6).
- You have severe kidney problems.
- You have asthma and you have previously experienced side effects to antihistamines.
- You are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).
- Safety and efficacy have not been established in children under the age of 2 years.

Warnings and precautions

Take special care with SEASONEZE:

- If you have problems passing urine (like spinal cord problems or prostate or bladder problems).
- If you have porphyria.
- If you have liver or kidney problems (see How to take SEASONEZE).
- It is advisable to avoid drinking alcohol with SEASONEZE.
- If you are an epileptic patient or a patient at risk of seizures, as you must be closely monitored.
- If you are scheduled for allergy testing, you must stop taking SEASONEZE at least 3 days before testing, as SEASONEZE may affect your allergy test results.

Children and adolescents

Children under the age of two years should not be given SEASONEZE as safety and efficacy have not been established.

SEASONEZE is not recommended for use in children aged less than 6 years as the formulation does not allow for proper dose adaptation. A paediatric formulation of cetirizine is recommended.

Other medicines and SEASONEZE

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

- Taking any other medicines that may make you drowsy (sedatives, tranquilisers or strong painkillers) with SEASONEZE is not advised.
- As with other antihistamines it is advisable to avoid excessive alcohol consumption.

SEASONEZE with alcohol

It is recommended to avoid taking SEASONEZE with alcohol.

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 taking SEASONEZE.

You should not take SEASONEZE if you are pregnant or breastfeeding your baby.

Driving and using machines

Caution is advised when driving a vehicle or operating machinery, as drowsiness may occur often with the use of SEASONEZE. You should not take more than the recommended doses as this may affect your ability to perform these tasks.

SEASONEZE contains lactose monohydrate

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

3. How to take SEASONEZE

Always take SEASONEZE exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults (including the elderly) and children 12 years of age or older:

The usual dose of SEASONEZE tablets is one tablet (10 mg) daily.

Children aged 6 to 12 years:

The usual dose of SEASONEZE tablets is one tablet (10 mg) daily or half a tablet (5 mg) twice daily.

If you have a liver or kidney disorder you should take half a tablet (5 mg).

Do not exceed the recommended dosage.

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

If you take more SEASONEZE than you should

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

Symptoms of overdose include confusion, diarrhoea, dizziness, fatigue, headache, malaise (feeling unwell), mydriasis (dilating pupils), pruritis (itching), restlessness and urinary retention (difficulty in completely emptying the bladder).

If you forget to take a dose of SEASONEZE

If you miss a dose of SEASONEZE, take that dose as soon as you remember. If your next dose is due within 6 hours, take this dose now and skip the next dose. Take your next dose at the normal time.

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

4. Possible side effects

SEASONEZE can have side effects.

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

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

- swelling of the 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

SEASONEZE. 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:

- frequent infections, such as fever, severe chills, sore throat or mouth ulcers,
- bleeding or bruising more easily than normal,
- convulsions (fits),
- recurring thoughts of harming or killing yourself,
- changes in the way your heart beats (beating faster or irregular),
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems,
- loss of bladder control or painful urination, difficulty in emptying the bladder.

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:

- sleepiness,
- dizziness,
- headache,
- pharyngitis,
- dry mouth,
- nausea (feeling sick),
- fatigue.

Less frequent side-effects:

- ringing in your ears,
- low blood pressure,
- sore throat, runny nose,
- stomach pain,
- increased appetite,
- agitation, aggression, confusion, depression, sleeplessness,
- seeing or hearing things that do not exist,
- repeated and involuntary twitches, movements, or sounds (tics),
- paraesthesia (tingling or numbness of your hands and feet (pins and needles)),
- dysgeusia (altered taste), dystonia (abnormal prolonged muscular contractions), dyskinesia (involuntary movements),
- stuffy nose, runny nose, sneezing and itching,
- thick mucous (phlegm),
- wheezing sound when breathing and coughing (bronchospasm),
- tremors (involuntary trembling or shaking of hands and feet),
- fainting,
- drowsiness,
- anxiety,
- nervousness,
- blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements),
- diarrhoea, nausea, stomach discomfort, constipation,
- lack of energy,
- sensitivity to light,

- loss of hair,
- increased sweating,
- feeling unwell,
- increased weight,
- abnormal liver function.

Side-effects with an unknown frequency:

- nightmare,
- memory loss or memory impairment,
- movement disorders,
- vertigo (sensation of spinning or swaying),
- pain in a joint.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SEASONEZE.

5. How to store SEASONEZE

- Store at or below 25 °C.
- Keep the tablets in the original packaging.
- Store all medicines out of reach of children.

- Do not use after expiry date printed on the tube or 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 SEASONEZE contains

The active substance is cetirizine dihydrochloride.

The other ingredients are: colloidal anhydrous silica, lactose monohydrate, magnesium stearate, microcrystalline cellulose, Opadry White Y-1-7000 (consisting of hypromellose, titanium dioxide, polyethylene glycol 400).

What SEASONEZE looks like and contents of the pack

SEASONEZE tablets are white to off white, round, film-coated tablets scored on the one side and plain on the other.

SEASONEZE tablets are available in white plastic bottles, patient ready packs or in clear plastic/silver aluminium blister packs containing 10, 20, 28, 30, 120 or 500 tablets.

Holder of certificate of registration

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