**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S2**

# ALERNOVA 0,5 mg/ml (ORAL SOLUTION)

**Levocetirizine Dihydrochloride**

**Contains sugar - Maltitol (400 mg/ml)**

**Contains preservative – Sodium Benzoate (4 mg/ml)**

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

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

**What is in this leaflet**

## 1. What ALERNOVA is and what it is used for

**ALERNOVA** contains a medicine called levocetirizine dihydrochloride. This belongs to a group of medicines called antihistamines.

**ALERNOVA** is used for the relief of symptoms associated with the following allergic conditions in adults and children:

- Seasonal allergic rhinitis - often referred to as hay fever and typically caused by outdoor allergens such as pollen from trees, grasses and weeds.
- Perennial allergic rhinitis - an inflammatory condition of the nose characterised by nasal obstruction, sneezing, itching, or runny nose, occurring for an hour or more on most days throughout the year.
- Chronic idiopathic urticaria - a chronic hive condition in which the cause is unknown.

## 2. What you need to know before you take ALERNOVA

**Do not take ALERNOVA:**

- If you are hypersensitive (allergic) to levocetirizine dihydrochloride, cetirizine, hydroxyzine or any of the other ingredients of ALERNOVA (listed in section 6).
- Infants and toddlers aged less than two years, as safety and efficacy have not been demonstrated.
- If you are pregnant or breastfeeding your baby.
- If you suffer from end stage kidney damage.

**Warnings and precautions**

**Take special care with ALERNOVA:**

- You may experience sedation (feel sleepy). This effect may be intensified by the simultaneous intake of alcohol or other central system depressants (such as antidepressants, anxiety medicines and sleeping tablets).
- If you suffer from urinary retention, a condition in which you cannot empty all the urine from your bladder (e.g., spinal cord lesion, prostatic hyperplasia). **ALERNOVA** may increase the risk of urinary retention.
- If you suffer from epilepsy or are at risk of convulsions (fits). **ALERNOVA** may cause worsening of seizures.
- If you are scheduled for allergy testing, stop taking **ALERNOVA** at least 3 days before testing. **ALERNOVA** may affect your allergy test results.

**Infants and children**

Do not give **ALERNOVA** to infants and toddlers aged less than 2 years.

**Other medicines and ALERNOVA**

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

Please inform your healthcare professional if you are currently taking any of the following medicines:

- Theophylline – used for the treatment of asthma.
- Ritonavir – used for the treatment of HIV.
- Central Nervous System (CNS) depressants such as antidepressants, anxiety medicines and sleeping tablets.

**ALERNOVA with food, drink or alcohol**

**ALERNOVA** can be taken with or without food.

Caution is advised if **ALERNOVA** is taken at the same time as alcohol or other medicines acting on the brain. In sensitive patients, the concurrent administration of **ALERNOVA** and alcohol or other medicines acting on the brain may lower your ability to be alert and to react.

**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 **ALERNOVA**.

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

Women of childbearing potential should consider the use of contraception (birth control medicine).

There is no information on how **ALERNOVA** will affect fertility.

**Driving and using machines**

You could experience sleepiness, fatigue and abnormal physical weakness or lack of energy while taking **ALERNOVA**. Therefore, if you are intending to drive, engage in potentially hazardous activities or operate machinery you should take your response to **ALERNOVA** into account.

**ALERNOVA contains maltitol and sodium benzoate**

**ALERNOVA** contains maltitol liquid. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking **ALERNOVA.**

**ALERNOVA** contains a preservative known as sodium benzoate. It may cause allergic reactions (possibly delayed), such as headache, stomach upset, and diarrhoea.

## 3. How to take ALERNOVA

Always take **ALERNOVA** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

**Adults and adolescents 12 years of age and older**

The daily recommended dose is 5 mg (10 ml) once daily.

**Children aged 6 - 12 years of age**

The daily recommended dose is 5 mg (10 ml) once daily.

**Children aged 2 - 6 years of age**

The daily recommended dose is 2,5 mg to be administered in 2 intakes of 1,25 mg (2,5 ml of oral solution twice daily).

**Children aged less than 2 years of age**

**ALERNOVA** is not recommended for use in infants and toddlers aged less than 2 years.

**Special dosage instructions for specific populations**

Elderly

Adjustment of your dose is recommended if you are elderly and suffer from moderate to severe renal impairment (the kidney's inability to perform its job).

Kidney impairment

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease. In children with impaired kidney function, the dose will also be chosen on the basis of body weight. The dose will be determined by your doctor. Patients who have severe impairment of kidney function must not take **ALERNOVA**.

Liver impairment

Patients who only have impaired liver function should take the usual prescribed dose.

If you have the impression that the effect of **ALERNOVA** is too strong or too weak, tell your doctor or pharmacist.

**If you take more ALERNOVA 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 ALERNOVA**

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

**If you stop taking ALERNOVA**

Intense itching (pruritus) may occur when **ALERNOVA** is stopped, even if those symptoms were not present before treatment with **ALERNOVA** was started. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment with **ALERNOVA** to be restarted. The symptoms should resolve when the treatment is restarted.

## 4. Possible side effects

**ALERNOVA** can have side effects.

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

If any of the following happens, stop taking **ALERNOVA** 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 reaction to **ALERNOVA**. You may need urgent medical attention.

Tell your doctor or health care provider if you notice any of the following:

Frequent:

- Headache
- Sleepiness
- Dry mouth
- Fatigue (tiredness)

Less frequent:

- Nausea
- Gastrointestinal discomfort (stomach cramps)
- Abnormal physical weakness or lack of energy
- A general feeling of discomfort, illness, or unease whose exact cause is difficult to identify

Frequency unknown:

- Convulsions (fits)
- Abnormal sensation, typically tingling or pricking (‘pins and needles’)

- Dizziness
- Temporary loss of consciousness caused by a fall in blood pressure
- Involuntary quivering movement
- Impairment of the sense of taste
- Vomiting
- Diarrhoea
- Swelling
- Hypersensitivity reactions
- Increased appetite
- Aggression
- Agitation
- Hallucination
- Depression
- Sleeplessness
- Suicidal thoughts
- Nightmares (sleep disorders)
- Sensation of whirling and loss of balance, associated particularly with looking down from a great height, or caused by disease affecting the inner ear or the vestibular nerve
- Visual disturbances
- Blurred vision
- Spasmodic movements of the eyeballs
- Palpitations
- Abnormally rapid heart rate (palpitations)
- Difficult or laboured breathing
- Hepatitis (inflammation in the liver)

- Painful or difficult urination
- Unable to empty all the urine from your bladder
- Pain in a muscle or group of muscles
- Pain in a joint
- Weight increased
- Abnormal liver function tests

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 ALERNOVA.

## 5. How to store ALERNOVA

Store all medicines out of sight and reach of children.

Store at or below 25 ºC (room temperature).

Keep the bottle tightly closed.

Store in the original package in order to protect from light.

Do not store in a bathroom.

Do not use **ALERNOVA** after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Return all unused medicines 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 ALERNOVA contains

- Each 1 ml oral solution contains 0,5 mg levocetirizine dihydrochloride.
- The other ingredients are liquid maltitol (E965), glycerol (E422), saccharin sodium, sodium acetate trihydrate, acetic acid (glacial), sodium benzoate (E211), wild strawberry aroma (flavouring substances, natural flavouring substances, propylene glycol (E1520), purified water.

### What ALERNOVA looks like

**ALERNOVA** is a clear and colourless oral solution with wild strawberry-like smell and flavour.

**ALERNOVA** is presented in a 200 ml brown glass bottle with a white or opaque polypropylene child-resistant closure. The bottle of solution is provided in a card box containing an oral syringe.

### Holder of Certificate of Registration

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