

PATIENT INFORMATION LEAFLET
FOR CETAWAY SOLUTION

SCHEDULING STATUS: **S2**

CETAWAY™ SOLUTION, 0,5 mg/ml oral solution

Levocetirizine dihydrochloride

Contains preservative sodium benzoate 0,4 % *m/v*

Contains maltitol liquid 400 mg/ml

Contains sweeteners glycerol 230 mg/ml and saccharin sodium 2 mg/ml

**Read all of this leaflet carefully before you start taking CETAWAY
SOLUTION**

CETAWAY SOLUTION is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CETAWAY SOLUTION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CETAWAY SOLUTION with any other person.
- Ask your healthcare 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 CETAWAY SOLUTION is and what it is used for
2. What you need to know before you take CETAWAY SOLUTION
3. How to take CETAWAY SOLUTION
4. Possible side effects
5. How to store CETAWAY SOLUTION
6. Contents of the pack and other information

1. What CETAWAY SOLUTION is and what it is used for

CETAWAY SOLUTION contains levocetirizine dihydrochloride, which is an antiallergic medicine. CETAWAY SOLUTION is used to treat symptoms associated with allergic conditions such as:

- hay fever
- year-round allergies such as dust or pet allergies
- nettle rash (urticaria).

2. What you need to know before you take CETAWAY SOLUTION

Do not take CETAWAY SOLUTION:

- if you are hypersensitive (allergic) to levocetirizine, or to other antihistamines called piperazine derivatives (such as buclizine, cetirizine, cyclizine), or any of the other ingredients of CETAWAY SOLUTION (see section 6)
- if you are pregnant, intend to become pregnant, or are breastfeeding your baby
- if you suffer from severe kidney failure (with creatinine clearance below 10 ml/min)
- Do not give CETAWAY SOLUTION to children younger than 2 years.

Warnings and precautions

Take special care with CETAWAY SOLUTION

- if you are likely to be unable to empty your bladder (due to conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice

- if you suffer from epilepsy or are at risk of convulsions, ask your doctor for advice as use of CETAWAY SOLUTION may cause seizure to be severe or occur more frequently
- if you are going for allergy testing, you should stop taking CETAWAY SOLUTION for at least 3 days before testing as CETAWAY SOLUTION will affect your allergy test results
- when you stop taking CETAWAY SOLUTION, you may experience itchy skin, even if it was not present before starting treatment. The itching may stop on its own, but in some cases, you experience intense itching and may need to restart treatment with CETAWAY SOLUTION.

Children

Do not give CETAWAY SOLUTION to children less than 2 years because it is unlikely to be safe.

Other medicines and CETAWAY SOLUTION

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

Please consult your healthcare provider for advice if you are taking any of the following medicine:

- theophylline, used to treat asthma and lung conditions, and ritonavir, used to treat HIV. These may increase the amount of CETAWAY SOLUTION in your body which increases the risk of side effects.

CETAWAY SOLUTION with food, drink and alcohol

CETAWAY SOLUTION may be taken with or without food.

Caution is advised if CETAWAY SOLUTION is taken at the same time with alcohol or other medicines acting on the brain (see Take special care with CETAWAY SOLUTION).

In sensitive patients, CETAWAY SOLUTION taken together with alcohol or other medicines acting on the brain may increase the side effects of levocetirizine such as dizziness, drowsiness and difficulty concentrating. Some people may also experience reduced alertness, impairment in thinking and judgement. You should avoid or limit the use of alcohol while being treated with CETAWAY SOLUTION.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking CETAWAY SOLUTION.

Driving and using machines

CETAWAY SOLUTION lacks significant sedative effects, however, you may experience drowsiness, tiredness and fatigue which may affect your ability to drive and use machines.

It is not always possible to predict to what extent CETAWAY SOLUTION may interfere with your daily activities. You should ensure that you do not engage in the above activities until they are aware of the measure to which CETAWAY SOLUTION affects you.

CETAWAY SOLUTION contains maltitol, liquid

CETAWAY SOLUTION contains maltitol, liquid and may have a laxative effect.

If you have been told that you have an intolerance to some sugars, you should not take CETAWAY SOLUTION.

3. How to take CETAWAY SOLUTION

Do not share medicines prescribed for you with any other person. Always take CETAWAY SOLUTION exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Adults and children from the age of 6 years

The usual dose is 10 ml solution once daily.

Children from the age of 2 to 6 years

The usual dose is 2,5 ml solution twice daily.

Do not give CETAWAY SOLUTION to infants and toddlers aged less than 2 years.

Special dosage instructions for specific populations

Kidney and liver problems

If you have impaired kidney or liver function or both, your doctor will determine the dose according to the severity of your condition. The dose in children will also be chosen on the basis of body weight by your doctor.

How and when should you take CETAWAY SOLUTION

This medicine is for oral use only.

A dosing syringe may be provided with the pack. You can take CETAWAY SOLUTION with or without food.

Handling of the dosing syringe

Place the dosing syringe into the bottle and draw the plunger up to the mark which corresponds to the dose in millilitres (ml) prescribed by your doctor.

Remove the dosing syringe from the bottle and empty its contents into a spoon by pressing the plunger down. Rinse the plunger with water after every use.

If you take more CETAWAY SOLUTION 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.

Symptoms of overdose may include:

- drowsiness can occur in adults
- children may initially show a sense of excitement (agitation) and restlessness followed by drowsiness.

If you forget to take CETAWAY SOLUTION

If you forget to take CETAWAY SOLUTION, take your next dose at your normal time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking CETAWAY SOLUTION

Stopping treatment should have no negative effects. However, rarely, you may experience intense itching (pruritus) if you stop taking CETAWAY SOLUTION, even if those symptoms were not present before you started treatment. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

4. Possible side effects

CETAWAY SOLUTION can have side effects.

Not all side effects reported for CETAWAY SOLUTION are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while taking CETAWAY SOLUTION, please consult your healthcare provider for advice.

If any of the following happens, stop taking CETAWAY SOLUTION 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 CETAWAY SOLUTION. 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:

- thinking about or feeling like you want to take your own life
- strong or irregular heartbeat, abnormally rapid heart rate
- difficulty breathing
- painful or difficult urination, passing less urine than is normal for you
- seizures (fits)

- liver infection (hepatitis) characterized by abdominal pain especially on the upper right side beneath your lower rib, dark urine, fever, yellowing of skin and eyes, which is sore when you press it (tenderness) on the right side just below your ribs and clay-coloured stool
- intense itching upon discontinuation.

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:

- headache
- sleepiness or drowsiness
- dry mouth
- diarrhoea
- constipation
- tiredness
- sleep disorders.

Less frequent side effects:

- nausea, abdominal pain
- abnormal physical weakness or lack of energy
- general feeling of discomfort.

Side effects with unknown frequency:

- weight gain, increased appetite
- aggression, agitation, seeing or hearing things that are not there (hallucination), depression, difficulty in falling and staying asleep (insomnia), nightmares

- tingling or prickling sensation (pins and needles), involuntary shaking (tremors), dizziness, distortion of sense of taste (dysgeusia)
- changes in vision, blurred vision
- sensation of spinning or feeling off balance
- vomiting
- swelling, redness and itchiness of the skin (urticaria)
- muscle pain, joint pain
- general swelling of ankles, feet and legs (oedema).

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 CETAWAY SOLUTION.

5. How to store CETAWAY SOLUTION

Store all medicines out of reach of children.

Store at or below 25 °C. Keep the bottle tightly closed.

Do not refrigerate. Keep in the original package.

6. Contents of the pack and other information

What CETAWAY SOLUTION contains

- The active substance is levocetirizine.
- The other ingredients are maltitol liquid (E965), glycerol (E422), saccharin sodium, sodium acetate trihydrate, glacial acetic acid, sodium benzoate (E211), wild strawberry aroma PHL-101104, water (purified).

What CETAWAY SOLUTION looks like and contents of the pack

CETAWAY SOLUTION is a clear and colourless oral solution, essentially free from particles, with a wild strawberry-like smell and flavour.

CETAWAY SOLUTION is packed in brown Type III glass bottles containing 60 ml, 100 ml, 150 ml or 200 ml solution and closed with a white polypropylene childproof screw cap.

The bottle is labelled and packed in a cardboard box with or without a calibrated oral syringe for dosing. The main graduation per 1 ml is marked on the syringe by bold line and number. Additional graduation per 0,5 ml is marked by a thin line.

Not all pack sizes are necessarily marketed.

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Access to the corresponding Professional Information

For professional information (PI) please contact
abex.regulatory@abexpharm.com.