PATIENT INFORMATION LEAFLET FOR CETAWAY:

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CETAWAY 5 mg film-coated tablets

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **CETAWAY** with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 days.

1. WHAT CETAWAY CONTAINS:

The active substance is levocetirizine dihydrochloride.

The other ingredients are colloidal silica anhydrous, lactose monohydrate, magnesium stearate, microcrystalline cellulose and Opadry white.

CETAWAY contains sugar: lactose monohydrate.

2. WHAT CETAWAY IS USED FOR:

CETAWAY is indicated for the relief of symptoms associated with the following allergic conditions in adults:

- Seasonal allergic irritation and inflammation of the nose.

- Allergic irritation and inflammation of the nose throughout the year.
- Daily, long term allergic irritation of the skin.

3. BEFORE YOU TAKE CETAWAY:

Do not take CETAWAY:

- If you are hypersensitive (allergic) to levocetirizine or any of the other ingredients of **CETAWAY** (see **WHAT CETAWAY CONTAINS**).
- If you are using any heart medication, antidepressants, antipsychotic medication or sexual enhancement medication with a substance derived from piperazine. Refer to your doctor for advice.
- If you have a sever kidney disease.
- If you are on dialysis.
- If you are pregnant or breastfeeding your baby.
- If you have been told by your doctor that you have an intolerance to some sugars
- Do not give **CETAWAY** to children.

Take special care with CETAWAY:

- **CETAWAY** may make you sleepy.
- Caution is advised if **CETAWAY** is taken at the same time as alcohol. In sensitive patients, the simultaneous use of **CETAWAY** and alcohol or medicines affecting the central nervous system may have effects on alertness and ability to drive and use machines.

Taking CETAWAY with food and drink:

- **CETAWAY** may be taken with or without food.
- It is advisable to avoid excessive alcohol consumption while taking **CETAWAY** at the same time, as the effect of alcohol may be increased or different than expected (see **Take special care**).

Pregnancy and Breastfeeding:

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

You should not take **CETAWAY** while you are pregnant or breastfeeding your baby, as safety has not been demonstrated.

The active ingredient is excreted in breastmilk and safety during breastfeeding has not been established.

Driving and using machinery:

Caution is advised when driving or using heavy machinery, as **CETAWAY** may cause drowsiness and fatigue.

Important information about some of the ingredients of CETAWAY:

CETAWAY contain lactose monohydrate. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **CETAWAY**.

Taking other medicines with CETAWAY:

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

No interaction studies have been done with the active ingredient, levocetirizine.

Caution is advised if **CETAWAY** is taken at the same time as alcohol (see **Take special care**).

4. HOW TO TAKE CETAWAY:

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

You should check with your doctor or pharmacist if you are unsure of how to take **CETAWAY**.

The film-coated tablet must be taken orally, swallowed with liquid and it is recommended to take the daily dose in one single intake.

Adults or children 12 years of age or older:

The usual dose is one 5 mg tablet.

Patients with liver disease:

No change in dosage is needed in patients with liver disease.

Patients with kidney disease:

If you have a severe kidney disease you should not take **CETAWAY** at all. If you are not sure contact your healthcare professional for advice.

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

If you take more CETAWAY than you should:

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

Drowsiness is an expected symptom of overdosage.

Overdosage in children may produce restlessness or agitation followed by drowsiness.

If you forget to take a dose of CETAWAY:

Take the tablet when you remember and carry on with normal directions of use from the next day.

5. POSSIBLE SIDE EFFECTS:

CETAWAY can have side effects.

Not all side effects reported for **CETAWAY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- irregular and/or fast heart beat
- shortness of breath or difficulty breathing
- if your liver function test came back abnormal or if your liver is inflamed (symptoms may include stomach pain or yellowing of the skin and whites of the eyes (jaundice))

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- increased weight
- difficulty sleeping, feeling aggressive, agitated, depressed or having hallucinations
- headaches, sleepiness, fits, prickly, tingly or numbness sensation of the skin, dizziness
- blurry vision or visual disturbances
- dry mouth, diarrhoea or constipation, nausea, vomiting or stomach pains
- hives or skin eruptions in the same place
- muscle aches
- painful urination
- feeling tired, weak or generally unwell

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

6. STORING AND DISPOSING OF CETAWAY:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Protect from moisture.

Keep blister strip in outer 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 and sewerage systems (e.g. toilets).

7. PRESENTATION OF CETAWAY:

CETAWAY is packed into two different blister strips:

- Silver OPA/Al/PVC and aluminium foil blister strips.
- Clear transparent PVC/PVDC and aluminium foil blister strips. 7 or 10 tablets are packed into a blister strip.
- 1 blister strip of 7 tablets is packed into an outer carton.
- 1 or 3 blister strips of 10 tablets are packed into an outer carton.

Please note that not all pack sizes and pack types are available.

8. IDENTIFICATION OF CETAWAY:

White, round, biconvex film-coated tablets with bevelled edges.

9. REGISTRATION NUMBER:

A46/5.7.1/0389

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Unicorn Pharmaceuticals (Pty) Ltd

8001

Cape Town

South Africa

11. DATE OF PUBLICATION:

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