PATIENT INFORMATION LEAFLET for ZELARY SYRUP

Scheduling Status:

S2

Proprietary name and Dosage form:

ZELARY SYRUP (1 mg/ml, syrup).

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **ZELARY SYRUP** 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 a few days.

WHAT ZELARY SYRUP CONTAINS

The active substance is cetirizine dihydrochloride.

Preservatives: Methyl hydroxybenzoate 0,135 % m/v and propyl hydroxybenzoate 0,015 % m/v.

The other inactive ingredients are acetic acid, banana flavouring, glycerol, purified water propylene glycol, saccharin sodium and sodium acetate.

ZELARY SYRUP contains sorbitol.

WHAT ZELARY SYRUP IS USED FOR

ZELARY SYRUP is indicated for symptomatic relief of allergic conditions such as allergic rhinitis, hay fever and allergic skin conditions associated with pruritus (itching) such as skin hives.

BEFORE YOU TAKE ZELARY SYRUP

Do not take ZELARY SYRUP:

- if you are hypersensitive (allergic) to cetirizine, hydroxyzine, any piperazine derivatives or any of the ingredients of **ZELARY SYRUP** (see "**What ZELARY SYRUP contains**").
- if you have severe kidney disease
- if you suffer from asthma and have had an allergic reaction to **ZELARY SYRUP**
- if you are pregnant or breastfeeding your baby (see "**Pregnancy and Breastfeeding**").
- in children under the age of 2 years, as safety and efficacy have not been demonstrated.

Take special care with ZELARY SYRUP:

- **ZELARY SYRUP** is a non-sedating medicine, however some patients may become drowsy after taking the syrup
- when taking **ZELARY SYRUP,** alcohol should not be consumed

- if you have any condition that results urinary retention (difficulty in emptying your bladder)
- if you are an epileptic patient (have fits), or a patient at risk of convulsions (fits)
- if you are scheduled for allergy testing, you should stop taking **ZELARY SYRUP** for several days before testing. This medicine may affect your allergy test results.
- Preservatives contained in **ZELARY SYRUP** may cause allergic reactions in certain patients.
- Elderly patients are more likely to experience side effects and must use **ZELARY SYRUP** as indicated only.
- Inform your doctor if you suffer from liver or kidney dysfunction.

Taking ZELARY SYRUP with food and drink:

ZELARY SYRUP can be taken with or without meals.

Pregnancy and breastfeeding:

ZELARY SYRUP should not be used if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding please consult your healthcare provider for advice before taking **ZELARY SYRUP**.

Driving and using machinery:

ZELARY SYRUP can lead to drowsiness and patients should be aware how they react to **ZELARY SYRUP** and exercise caution before driving, operating dangerous machinery or performing dangerous tasks.

Important information about some of the ingredients

ZELARY SYRUP contains sorbitol and may have a laxative effect. If you have been told that you have an intolerance to some sugars, you should not take **ZELARY SYRUP.**

Using other medicines with ZELARY SYRUP:

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

- Taking any medicines that may make you drowsy (such as sedatives, tranquilizers, sleeping tablets or strong pain killers) with **ZELARY SYRUP** is not advised.
- Alcohol should be avoided while using **ZELARY SYRUP.**

HOW TO USE ZELARY SYRUP

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

Always take **ZELARY SYRUP** exactly as your doctor has instructed you.

You should check with your doctor if you are unsure.

Adults or children 12 years of age or older:

10 mg (10 ml) daily.

Children 6 to 12 years old:

10 mg (10 ml) daily, either as a single dose or as divided doses of *5* ml in the morning and 5 ml in the evening.

Children 2 to 6 years old:

5 mg (5 ml) daily, either as a single dose or as divided doses of 2,5 ml in the morning and 2,5 ml in the evening.

If you take more ZELARY 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.
Symptoms of overdosage may include feeling sleepy or tired, agitated, a skin rash, passing less urine than is normal for you, uncontrolled trembling or shaking, rapid heartbeat.

If you forget to take ZELARY SYRUP:

If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next dosage at the usual time.

POSSIBLE SIDE EFFECTS

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

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

- Swelling of the hands, feet, ankles, difficulty in breathing, with or without swelling of face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps)

These are all very serious side effects. If you have them, you may have had a serious allergic **ZELARY SYRUP.** 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:

- yellowing of skin and eyes, also called jaundice.
- fainting
- seizures (fits)
- fast, pounding or irregular heartbeat.
- passing less / more urine than is normal for you
- hallucinations (seeing and hearing things that aren't there)
- blurred vision, difficulty focussing, rolling of the eyes, low blood pressure (light-headedness, dizziness)

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

Tell your doctor if you notice any of the following:

The following side effects are frequently experienced with the use of **ZELARY SYRUP**:

- sore throat
- cold-like symptoms

Other less frequent side effects associated with the use of **ZELARY SYRUP** include:

- anaemia with symptoms such as fatigue, pale skin or other abnormal blood test results
- increased appetite, weight gain
- unusual tiredness or weakness, inability to sleep (insomnia)
- depression, confusion, aggression, agitation, diminishing memory
- feeling sleepy or drowsy
- headache, dizziness, anxiety, nervousness,
- sensations of tingling, burning, pricking (pins and needles), or numbness of the skin
- twitching, uncontrolled trembling or shaking, memory loss
- vertigo (spinning head), ringing or buzzing in the ears
- thickening of mucous, cough
- nausea, constipation, dry mouth, diarrhoea, abdominal pain, bloating, excess gas (wind)
- abnormal liver test results
- skin rashes or other skin conditions such as sensitivity to light, sweating, hair loss,

- muscle pain
- difficult or painful urination
- generally feeling unwell, weak, lack of energy, swelling in any part of the body (water retention)

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

STORING AND DISPOSING OF ZELARY SYRUP

Store in a dry place at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the syrup after the expiry date printed on the containers.

Decomposed products may be toxic.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

PRESENTATION OF ZELARY SYRUP

Type 3 amber glass bottle with a tamper evident, white coloured polyethylene closure, contained in a printed outer carton.

Pack sizes: 50 ml, 100 ml, 150 ml and 200 ml

IDENTIFICATION OF ZELARY SYRUP

Clear or almost clear colourless solution with taste and odour of banana.

REGISTRATION NUMBER

41/5.7.1/0085

NAME AND ADDRESS OF REGISTRATION HOLDER

Unicorn Pharmaceuticals (Pty) Ltd.

Corner Searle and Pontac Streets

Cape Town

8001

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