Applicant/PHRC: ***Hetero Drugs South Africa (Pty) Ltd***

Product proprietary name: ***ZIALDEL***

Dosage form and strength: Oral solution, Each 5 ml contains 5 mg cetirizine dihydrochloride

APPROVED PATIENT INFORMATION LEAFLET FOR ZIALDEL

SCHEDULING STATUS

S2

ZIALDEL ORAL SOLUTION 5 mg/5mL

Cetirizine dihydrochloride

Each ml contains 2,7 g sorbitol (sugar),

2,5 mg sucralose (sweetener) and

0,2 % m/v sodium benzoate (preservative)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ZIALDEL 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 ZIALDEL is and what it is used for
2. What you need to know before you use ZIALDEL
3. How to use ZIALDEL
4. Possible side effects
5. How to store ZIALDEL
6. Contents of the pack and other information

1. What ZIALDEL is and what it is used for

The active ingredient is cetirizine dihydrochloride, and it Belongs to a group of medicines called antihistamines. ZIALDEL is used for the treatment of allergies, including:

- Allergic rhinitis and hay fever - an allergic response which causes itchy, watery eyes, sneezing, runny nose.
- Allergic skin conditions that cause itching, swelling, and redness of the skin.

2. What you need to know before you use ZIALDEL

Do not use ZIALDEL:

- If you are hypersensitive (allergic) to cetirizine dihydrochloride, hydroxyzine, any piperazine derivatives or any of the other ingredients of ZIALDEL (see **ZIALDEL contains**).
- If you have severe kidney problems.
- If you suffer from asthma and have previously experienced side effects to antihistamines.
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- Do not give ZIALDEL to your child if he or she is younger than 2 years.

Warnings and precautions

ZIALDEL is a non-sedating medicine, however some patients may become drowsy after taking the medicine (see Driving and using machinery).

Take special care with ZIALDEL:

- If you have kidney problems.
- If you have liver problems.
- If you are an epileptic or at risk of convulsions (fits).
- ZIALDEL can interfere with the test results of an allergy skin test. It is recommended to stop taking ZIALDEL 3 days prior to your scheduled allergy skin test.

If you have any problems with passing urine, speak to you doctor before taking ZIALDEL.

Children and adolescents

- Do not give ZIALDEL to your child if he or she is younger than 2 years.

Other medicines and ZIALDEL

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

Due to the profile of cetirizine, no interactions with other medicines are expected.

ZIALDEL with food, drink and alcohol

ZIALDEL can be taken with or without food. Do not consume alcohol while taking ZIALDEL.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult our doctor or other healthcare provider for advice before taking ZIALDEL. Do not use [PN] if you are pregnant.

ZIALDEL passes into breast milk. Side effects associated with ZIALDEL may be seen in breastfed infants. Therefore, you should not take ZIALDEL during breastfeeding (see Do not use ZIALDEL).

Driving and using machines

ZIALDEL does not produce remarkable drowsiness. However, ZIALDEL may cause drowsiness in some patients. ZIALDEL may cause dizziness and can affect your ability to drive a vehicle and use machines (see POSSIBLE SIDE EFFECTS). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ZIALDEL affects you.

ZIALDEL contains Sorbitol

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive ZIALDEL.

3. How to use ZIALDEL

Do not share medicines prescribed for you with any other person. Always use ZIALDEL exactly as prescribed in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults and children over the age of 12 years:

The usual dose is 10 ml (10 mg) once daily.

Children 6 to 12 years of age:

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

Children 2 to 6 years of age:

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

Elderly patients:

No dose adjustment is necessary if you are an elderly patient with normal renal function. If you have liver or kidney problems your doctor will adjust your dose accordingly. If your symptoms do not improve or get worse, speak to your doctor.

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

If you take more ZIALDEL than you should

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

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating (widening) of the pupil, itching, restlessness, sleepiness, stupor (lowered consciousness), abnormal rapid heart rate, tremors and urinary retention may occur.

If you forget to use ZIALDEL

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take ZIALDEL at the next regularly scheduled time.

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

If you stop taking ZIALDEL

Pruritus (itching) and/ or urticaria (skin rash) may occur when cetirizine as in ZIALDEL is stopped, even if those symptoms were not present before treatment initiation. 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

ZIALDEL can have side effects.

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

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

- Swelling of your 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 ZIALDEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at our nearest hospital if you notice any of the following:

- Signs of recurrent infections, such as fever and a sore throat.
- Bleeding or bruising more easily than normal.
- Convulsions (fits/seizures).
- Fast or irregular heartbeat.
- Liver disorders including increase in liver enzymes and bilirubin when blood tests are done (dark urine, light-coloured, bloody or black stools, loss of appetite).
- Painful urination or difficulty in passing urine, inability to control urination.

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

Tell your doctor if you notice any of the following:

Frequent:

- Drowsiness, dizziness, headache.
- Runny nose, sore throat.
- Dry mouth, nausea (feeling sick), vomiting (being sick), diarrhoea.
- Tiredness, weakness.

Less frequent:

- Feeling depressed, confused.
- Inability to sleep.
- Tingling or numbness of your hands and feet (pins and needles).
- Tremors (involuntary trembling or shaking of hands and feet).
- Ringing sounds in the ear (tinnitus).
- Low blood pressure (characterised by light-headedness).
- Changes in heart rate.
- Stomach pain, constipation.
- Hair loss (temporary), sweating, sensitive to sunlight.
- Pain in a muscle or a group of muscles, muscle spasms.
- Increase in weight.

Frequency unknown:

- Feeling agitated, aggressive.
- Seeing, feeling or hearing things that are not there.
- Uncontrollable twitching or jerking movements.
- Experiencing nightmares and thoughts of hurting yourself.
- Foul, salty or metallic taste in your mouth.
- Fainting.
- Loss of memory.
- Problems with seeing clearly, blurred vision.
- Abnormal physical weakness or lack of energy.
- Generally feeling unwell.
- Increase in appetite.

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 or nurse. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reactions Form", found online under SAHPRA's https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/

or to the Holder of certificate of registration through the mail:pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of ZIALDEL.

5. How to store ZIALDEL

- Store at or below 25 °C. Protect from light.
- Keep in the original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the bottle.
- 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 ZIALDEL contains

The active substance is cetirizine dihydrochloride.

Each 5 ml contains 5 mg cetirizine dihydrochloride.

The other ingredients are sodium benzoate, sucralose, sorbitol anhydrous citric acid, purified water, ART Grape FL # 10273 and propylene glycol.

What ZIALDEL looks like and contents of the pack

Clear, colourless to yellow grape flavoured liquid.

150 ml white, opaque, round PP bottle with a white, opaque PP child-resistant ribbed, plastic cap with opening illustrations embossed on the top, packed in an outer cardboard carton with 118mL fill

volume.

Holder of Certificate of Registration

Hetero Drugs South Africa (Pty) Ltd

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Registration number

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Access to the corresponding Professional Information

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