Package leaflet: Information for the user
Zirpine 1 mg/ml Oral Solution
cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Zirpine is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Zirpine. Zirpine is an antiallergic medication.

In adults and children aged 2 years and above, Zirpine is indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

2. What you need to know before you take Zirpine

Do not take Zirpine
- if you have a severe kidney disease requiring dialysis;
- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Zirpine if you:

- are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.
- have problems passing urine (like spinal cord problems or prostate or bladder problems).
- are an epileptic patient or a patient at risk of convulsions.
- your symptoms persist, you should get advice from your doctor or pharmacist.
- you are due to have an allergy test, as this medicine may affect your allergy test result.

Other medicines and Zirpine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Zirpine with food and drink
Food does not affect absorption of Zirpine.
It is recommended to avoid alcohol consumption while you are taking this medicine, as is the case with all antihistamine medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Zirpine should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the medicine should only be administered if necessary and after medical advice.

Cetirizine dihydrochloride passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Zirpine during breast-feeding unless you have contacted a doctor.

Driving and using machines
Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zirpine at the recommended dose.

You should closely observe your response to the drug after you have taken Zirpine if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Important information about some of the ingredients of Zirpine
Zirpine contains:

- sorbitol (E420): this medicine contains 450 mg sorbitol in each ml. 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 this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- propylene glycol: this medicine contains 50 mg propylene glycol in each ml.
- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).
- sodium: this medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.
- ethanol: this medicine contains 0.00525 mg of alcohol (ethanol) in each ml which is equivalent to 0.000525 w/v%. The amount in 10 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- benzyl alcohol: this medicine contains 0.00001575 mg benzyl alcohol in each ml. Benzyl alcohol may cause allergic reactions. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in our body and may cause side

effects (called “metabolic acidosis”). Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to take Zirpine

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

The measuring spoon provided is double-ended. The larger spoon holds 5 ml of your medicine, and the smaller spoon holds 2.5 ml. Each 5 ml spoonful of solution contains 5 mg cetirizine dihydrochloride. Each 2.5 ml spoonful of solution contains 2.5 mg cetirizine dihydrocholoride. The usual dose is:

Adults, the elderly and children aged 12 years and above:	Two 5 ml spoonfuls once daily (a maximum of 10 ml daily).
Children aged 6 to 12 years:	One 5 ml spoonful twice daily (a maximum of 10 ml daily).
Children aged 2 to 6 years:	One 2.5 ml spoonful twice daily (a maximum of 5 ml daily).

Patients with renal impairment
Patients with moderate renal impairment are recommended to take 5 ml once daily.

If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.

If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child’s needs.

If you feel that the effect of Zirpine is too weak or too strong, please consult your doctor.

Duration of treatment
The duration of treatment depends on the type, duration and course of your complaints. Please ask your doctor or pharmacist for advice.

If you take more Zirpine than you should
If you or your child may have taken too much of this medicine, talk to a doctor or pharmacist immediately.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in emptying the bladder) have been reported.

If you forget to take Zirpine
Do not take a double dose to make up for a forgotten dose.

If you stop taking Zirpine
Rarely, pruritus (intense itching) and/or urticaria (hives) may return if you stop taking Zirpine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Zirpine can cause side effects, although not everybody gets them.

The following side effects are rare or very rare, but you must stop taking the medicine and speak to your doctor immediately if you notice them:
– Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).
These reactions may start soon after you first take the medicine, or might start later.

Common side effects (may affect up to 1 in 10 people)
– Somnolence (sleepiness)
– Dizziness, headache
– Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)
– Diarrhoea, nausea, dry mouth
– Fatigue

Uncommon side effects (may affect up to 1 in 100 people)
– Agitation
– Paraesthesia (abnormal feelings of the skin)
– Abdominal pain
– Pruritus (itchy skin), rash
– Asthenia (extreme fatigue), malaise (feeling unwell)

Rare side effects (may affect up to 1 in 1000 people)
– Allergic reactions, some severe (very rare)
– Depression, hallucination, aggression, confusion, insomnia
– Convulsions
– Tachycardia (heart beating too fast)
– Liver function abnormal
– Urticaria (hives)
– Oedema (swelling)
– Weight increased

Very rare side effects (may affect up to 1 in 10,000 people)
– Thrombocytopenia (low levels of blood platelets)
– Tics (habit spasm)
– Syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)

- Blurred vision, accommodation disorder (difficulty focusing), oculogyric crisis (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

Not known (frequency cannot be estimated from the available data)
- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia (memory loss), memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Hepatitis (inflammation of the liver)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zirpine

Keep out of the sight and reach of children, and do not store above 25˚C.

Do not use Zirpine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Do not use after 6 months of first opening the bottle. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zirpine contains
- The active ingredient is cetirizine dihydrochloride: 1 mg in each ml of solution.
- The other ingredients are: liquid sorbitol (E420), glycerol, propylene glycol, sodium acetate, acetic acid, saccharin sodium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), banana flavour and purified water.

What Zirpine looks like and contents of the pack
Zirpine is a clear or almost clear colourless solution, with the taste and smell of banana. It is available in pack sizes of 100 ml and 200 ml amber glass bottles, and includes a combined 2.5 ml /5 ml measuring spoon.

Marketing Authorisation Holder and Manufacturer
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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