CETIRIZINE PHENYLEPHRINE HCl

ZYRIZ PLUS

5 mg / 5 mg per 5 mL Syrup

ANTIHISTAMINE / NASAL DECONGESTANT

FORMULATION
Each 5 mL (1 Teaspoonful) Syrup contains:
Cetirizine dihydrochloride ..... 5 mg
Phenylephrine hydrochloride ..... 5 mg

PRODUCT DESCRIPTION
Clear, colorless to slightly yellow syrup with banana flavor and characteristic odor

WHAT IS IN THE MEDICINE?
This medicine contains Cetirizine and Phenylephrine HCl.

Cetirizine, a piperazine derivative and metabolite of hydroxyzine. It is described as a long-acting, less sedating anti-allergy medicine. It appears to have a low potential for drowsiness in usual doses. It blocks the action of a chemical messenger (histamine) responsible for runny nose, watery eyes and sneezing.

Phenylephrine is a decongestant which provides temporary relief from congestion or stuffiness in the nose.

STRENGTH OF THE MEDICINE
See Formulation

WHAT IS THIS MEDICINE USED FOR?
This medication is used for the relief of runny nose, itchy nose, itchy throat, clogged nose, sneezing, and itchy or watery eyes associated with allergic rhinitis. It is also used for the relief of swollen, pale red bumps (hives or urticaria) caused by allergic reactions.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
This medicine should be taken by mouth (orally) every 12 hours, or, as directed by your physician.

Children 2 to 5 years old	2.5 mL (1/2 teaspoonful)
Children 6 to 12 years old	5 mL (1 teaspoonful)

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
Do not give this medicine due to Cetirizine content if the child has:
- Allergy to Cetirizine or any ingredient of the product.
- Hypersensitivity to cetirizine dihydrochloride, to hydroxyzine, to any piperazine derivatives medication

Do not give this medicine due to Phenylephrine content if the child has:
- Allergy to Phenylephrine or any ingredient of the product.
- Cardiovascular disease
- Elevated blood pressure
- Diabetes mellitus
- Closed-angle glaucoma
- Thyroid disorder
- Pheochromocytoma
- Mental or mood disorders
- Difficulty in urinating (e.g. prostate problems)

UNDESIRABLE EFFECT OF THIS MEDICINE?
Cetirizine:
The following most common undesirable effects linked to Cetirizine may occur including:
- Fatigue
- Dizziness
- Headache
- Abdominal pain
- Xerostomia (Dry mouth)
- Somnolence (Sleepiness)
- Pharyngitis (Inflammation of the back of the throat)

In addition to the undesirable effects reported and listed above, the following undesirable effects have been reported but were not recognized as to whether it has a direct relation to the use of Cetirizine.

Blood and lymphatic system disorders
Very rare: thrombocytopenia

Immune system disorders
Rare: hypersensitivity
Very rare: anaphylactic shock

Metabolism and nutrition disorders
Not known: increased appetite

Psychiatric disorders
Uncommon: agitation
Rare: aggression, confusion, depression, hallucination, insomnia
Very rare: tics
Not known: suicidal ideation, nightmare

Nervous system disorders
Uncommon: paraesthesia
Rare: convulsions
Very rare: syncope, dysgeusia, tremor, dystonia, dyskinesia
Not known: amnesia, memory impairment

Eye disorders
Very rare: accommodation disorder, blurred vision, oculogyration

Ear and labyrinth disorders
Not known: vertigo

Cardiac disorders
Rare: tachycardia

Gastrointestinal disorders
Uncommon: diarrhoea

Hepatobiliary disorders
Rare: abnormal hepatic function (increased transaminases, alkaline phosphatase, gamma-GT and bilirubin)
Not known: hepatitis

Skin and subcutaneous tissue disorders
Uncommon: rash, pruritus
Rare: urticaria
Very rare: angioneurotic edema, fixed drug eruption
Not known: acute generalized exanthematous pustulosis

Musculoskeletal and connective tissue disorders
Not known: arthralgia

Renal and urinary disorders
Very rare: dysuria, enuresis
Not known: urinary retention

General disorders and administration site conditions
Uncommon: asthenia, malaise
Rare: edema

PHENYLEPHRINE HCl:
The following most common undesirable effects linked to Phenylephrine may occur including:
- Trouble sleeping
- Dizziness
- Lightheadedness
- Headache
- Nervousness
- Shaking
- Palpitations
- Fast and irregular heartbeat

WHAT OTHER MEDICINES OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Phenylephrine
Should not be given to patients being treated with Monoamine Oxidase Inhibitors or within 14 days of stopping such treatment.

May enhance the effects of anticholinergic drugs such as tricyclic antidepressants

May increase the possibility of arrhythmias in digitalised patients (patients who are taking Digoxin or digitalis-containing medications).

May enhance the cardiovascular effects of other decongestants

This medicine should not be taken together with vasodilators, Beta-blockers or enzyme inducers such as alcohol.

Cetirizine
Cetirizine may enhance the effects of the following medications:
- Barbiturates,
- Hypnotics,
- Opioid analgesics
- Anxiolytic sedatives
- Monoamine Oxidase Inhibitors (MAOIs)
- Atropine

Cetirizine can also mask the symptoms of ototoxicity (damage to the inner ear, resulting in damage to the organs responsible for hearing and balance) in aminoglycosides antibiotics including gentamicin, amikacin, tobramycin, neomycin, and streptomycin.

Inform your physician if the child is taking other medication. Including other medicines for cough, cold or allergy. Food does not affect absorption of Cetirizine and Phenylephrine.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If the child misses a dose, just give the next dose if still needed for the condition being treated, and the subsequent doses at the recommended time or schedule (i.e. every 12 hours).

Do not double the dose.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Cetirizine
Symptoms observed after an overdose of Cetirizine includes confusion, diarrhea, dizziness, fatigue, headache, malaise (feeling of discomfort), mydriasis (widening of the pupils), itchiness, restlessness, sleepiness, stupor (state of near-unconsciousness), tachycardia (fast heartbeat), tremor (rhythmic shaking movement in one or more parts of your body), and urinary retention.

Phenylephrine
Symptoms observed after an overdose of Phenylephrine includes headache, hypertension, reflex bradycardia (decrease heart rate), tingling limbs, cardiac arrhythmias (group of conditions that cause the heart to beat irregularly, too slowly, or too quickly), and a feeling of fullness in the head.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If the child has taken more than the recommended dosage, consult a physician.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?
Cetirizine
Dosage adjustment is necessary in patients with moderate or severe renal impairment.

Caution should be taken in patients with urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. The symptoms should resolve when the treatment is restarted.

Phenylephrine
This medicine should be used with caution in patients with Raynaud's Phenomenon (The skin of the affected part of the body turns to white, blue or red due to less blood flow on the affected area in response to cold and other factors.)

Patients with rare hereditary problems including galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Do not use it after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR PHYSICIAN?
Advise the physician if the child has the following before using this medicine:
- Cardiovascular problems
- Elevated blood pressure
- Hyperactive thyroid
- Mental or mood disorders
- Difficulty in urinating
- Diabetes
- Glaucoma

If symptoms do not improve or new symptoms occur, consult a physician.

ADVERSE DRUG REACTION REPORTING
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

HOW SHOULD YOU KEEP THIS MEDICINE?
Store at temperatures not exceeding 30°C.

Keep medicine out of reach of children.

AVAILABILITY
ZyrizPlus (Cetirizine + Phenylephrine HCl) 5 mg/ 5 mg per 5 mL Syrup 60 mL (Banana Flavor) and 10 mL (Physician's Sample)

Marketing Authorization Holder
THE CATHAY YSS DISTRIBUTORS CO., INC.
2/F Vernida I Condominium, 120 Amorsolo St., Legaspi Village, Makati City

Manufacturer
HIZON LABORATORIES, INC.
Assumption Road, Sumulong Highway, Antipolo, Rizal

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