Type A-10a: Addition of container presentation size, 10's, same container & closure system.
Amendment date: July 2016
24 November 2017: Transfer of Applicancy

ZINALLERG

a) Package Insert:

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorise any deviation from such information or such format (refer to Regulation 9 of the Act).

1 Scheduling status
2 Proprietary name and dosage form
3 Composition
4 Pharmacological classification
5 Pharmacological action
(Pharmacokinetics, pharmacodynamics and summary of clinical studies, where applicable)
6 Indications
7 Contraindications
8 Warnings
9 Interactions
10 Pregnancy and lactation
11 Dosage and directions for use
12 Side effects and special precautions
13 Known symptoms of overdosage and particulars of its treatment
14 Identification
15 Presentation
16 Storage instructions
17 Registration number
18 Name and business address of the holder of the certificate of registration
19 Date of publication of the package insert

ZINALLERG

SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):

ZINALLERG (FILM-COATED TABLETS)

COMPOSITION:

Each film-coated tablet contains

Cetirizine dihydrochloride 10 mg

Contains lactose monohydrate.

The other ingredients are: Cellulose, microcrystalline (Avicel PH 102), magnesium stearate, opadry II OY GM 28900 white and silica colloidal anhydrous.

The opadry II OY GM 28900 white consists of hypromellose, polydextrose, polyethylene glycol and titanium dioxide.

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:

Pharmacodynamics

Cetirizine, a metabolite of hydroxyzine, is an anti-allergic agent with a histamine H1 receptor antagonism devoid of any significant anticholinergic and antiserotonin effects. The anti-allergic

activity seems to be exerted mainly via its effects on the release of certain mediators, such as histamine, together with a selective action on the H1 receptors. Cetirizine reduces eosinophil recruitment induced by an antigen-antibody reaction.

Pharmacokinetic properties:

Peak blood levels of 300 ng/ml are reached within one hour after oral administration of cetirizine. Cetirizine does not undergo extensive first pass metabolism. The terminal half-life is approximately 10 hours in adults, 6 hours in children aged 6 to 12 years and 5 hours in children aged 2 to 6 years.

These findings are consistent with the urinary excretion half-life of cetirizine. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children. The apparent plasma clearance in children is higher than that measured in adults. Plasma levels are linearly related to the dosage given. A high proportion of cetirizine is bound to human plasma proteins. In patients with impaired renal clearance (less than 40 ml/min) and hepatic insufficiency, an increase in half-life and decrease in total creatinine clearance occurs.

INDICATIONS:

Allergic processes responding to a histamine H1 receptor antagonist.

– Respiratory Allergic rhinitis, hay fever.

:

– Cutaneous: Allergic skin conditions associated with pruritus e.g. urticaria.

CONTRAINDICATIONS:

History of hypersensitivity to any of the constituents of the formulation.

Hypersensitivity to hydroxyzine.

ZINALLERG is contraindicated in breastfeeding women since the active ingredient is excreted in breast milk.

ZINALLERG is contraindicated in pregnancy as the safety has not been established.

WARNINGS:

ZINALLERG lacks significant sedative effects. **ZINALLERG** may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

INTERACTIONS:

Studies with diazepam, glipizide, pseudoephedrine, ketoconazole, azithromycin, erythromycin and cimetidine have revealed no evidence of pharmacokinetic interactions. It is advisable to avoid excessive alcohol consumption.

PREGNANCY AND LACTATION:

The safety of **ZINALLERG** in pregnant and breastfeeding women has not been established (see Contraindications).

DOSAGE AND DIRECTIONS FOR USE:

Tablets:

- Adults, or children 12 years of age or older: one 10 mg tablet daily.
- Children 6 to 12 years old: 10 mg (1 tablet) once daily or 5 mg (half a tablet) twice daily.

No dose reduction is required in elderly patients with normal renal function. In patients with renal insufficiency (creatinine clearance less than 40 ml/min), the dosage should be reduced to half the

usual recommended dose. Half the recommended daily dose should be used in patients with moderate to severe hepatic impairment.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects

Nervous system disorders:

Frequent: Headache, dizziness, lassitude, incoordination.

Less frequent: Convulsions, sweating, paraesthesias, extrapyramidal effects, tremor.

Frequency unknown: Drowsiness, nervousness.

Psychiatric disorders:

Less frequent: Agitation, sleep disturbances, depression, confusion.

Gastrointestinal disorders:

Frequent: Dry mouth, nausea, constipation, increased gastric reflux.

Less frequent: Vomiting, diarrhoea, epigastric pain.

Frequency unknown: Increased appetite, gastrointestinal discomfort.

Hepatobiliary disorders:

Frequency unknown: Hepatitis.

Eye disorders:

Frequent: Blurred vision.

Renal and urinary disorders:

Frequent: Urinary difficulty or retention.

Musculoskeletal, connective tissue and bone disorders:

Frequent: Psychomotor impairment.

Less frequent: Myalgia.

Blood and the lymphatic system disorders:

Less frequent: Agranulocytosis, leucopenia, haemolytic anaemia, thromobocytopenia.

Ear and labyrinth disorders:

Less frequent: Tinnitus.

Vascular disorders:

Less frequent: Hypotension.

General disorders and administrative site conditions:

Frequent: Fatigue.

Less frequent: Asthenia, malaise, hair loss, sweating.

Immune system disorders:

Less frequent: Hypersensitivity reactions including bronchospasm, angioedema and anaphylaxis.

Skin and subcutaneous tissue disorders:

Less frequent: Skin reactions, urticaria, pruritus.

Special precautions

ZINALLERG lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

ZINALLERG contains lactose and should not be given to patients with rare hereditary problems, or a history of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Drowsiness can be a symptom of overdosage. Overdosage in children may produce agitation, somnolence, pruritus, rash, urinary retention, fatigue, tremor, and tachycardia. In the case of massive overdosage, gastric lavage should be performed together with the usual supportive measures. To date there is no specific antidote. Cetirizine is not effectively removed by dialysis.

IDENTIFICATION:

ZINALLERG: White to off white, film-coated capsule shaped tablets, one face of the tablet plain and break line on the other.

PRESENTATION:

ZINALLERG tablets are available in clear PVC/PVDC and printed aluminium blister packs of 15 tablets. 2 blister packs are packed in an outer box.

ZINALLERG tablets are also available in clear PVC/PVDC and printed aluminium blister packs of 10 tablets. 1 blister pack is packed in an outer box.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Keep tablets in a dry place.

Keep the blisters in the carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

43/5.7.1/0359

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Oethmaan Biosims (Pty) Ltd

14 Komatie Road

Emmarentia

Johannesburg

2195

DATE OF PUBLICATION OF THE PACKAGE INSERT:

15 August 2013