SCHEDULING STATUS: S2

PROPRIETARY NAME (AND DOSAGE FORM):
ALLERMINE TABLETS (Film-coated tablets)

COMPOSITION :
Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
Contains sugar: 74,30 mg lactose monohydrate.

PHARMACOLOGICAL CLASSIFICATION:
A 5.7.1 Antihistaminics.

PHARMACOLOGICAL ACTION:
Cetirizine is a metabolite of hydroxyzine. It is a second-generation reversible, competitive inhibitor of histamine at the histamine- 1 (H1) receptor. Cetirizine competes with histamine for the H1-receptor site. Cetirizine prevents, but does not reverse, pharmacological responses mediated by histamine, at the H1-receptor.

Pharmacokinetics:
Cetirizine is well absorbed from the gastro-intestinal tract and peak plasma concentrations are reached within 1 hour after oral administration. Pharmacokinetics are linear, with plasma concentrations increasing proportionately with increasing doses. The terminal half-life in adults is approximately 10 hours; in children aged 6 to 12 years, 6 hours; in children aged 2 to 6 years, 5 hours. Cetirizine is eliminated faster in children, and slower in patients with hepatic or renal impairment (creatinine clearance < 40 ml/min), with a resultant increase in half-life and decrease in clearance. Cetirizine does not undergo extensive first-pass metabolism. The cumulative urinary excretion represents about two thirds of the dose given in both adults and children.

INDICATIONS:
ALLERMINE Tablets are indicated for symptomatic relief of allergic conditions such as allergic rhinitis, and allergic skin conditions such as urticaria.

CONTRAINDICATIONS:
Hypersensitivity to any of the ingredients. Hypersensitivity to hydroxyzine. Lactating women, since the active ingredient is excreted in breast milk. Pregnancy, as safety has not been established. Children under the age of two years, as safety and efficacy have not been demonstrated.

WARNINGS:
This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. The patient's ability to perform hazardous activities requiring mental alertness or physical coordination such as driving or operating machinery may be impaired.
Porphyria: Use with caution.

INTERACTIONS:
Concomitant use of alcohol and other sedating agents should be avoided. There is no evidence of an interaction between cetirizine and cimetidine, ketoconazole, erythromycin, azithromycin, diazepam, glipizide, and pseudoephedrine.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established (see "**CONTRAINDICATIONS**").

DOSAGE AND DIRECTIONS FOR USE:
Adults or children 12 years of age or older: One 10 mg tablet once daily.
Children 6 to 12 years old: One 10 mg tablet once daily or 5 mg (half a tablet) twice daily. No dose adjustment is necessary in healthy elderly patients with normal renal function.

Dosage in Renal impairment:
In patients with renal impairment, where the creatinine clearance is less than 40 ml/min, the recommended daily dose of cetirizine should be halved.

Dosage in Hepatic impairment:
In moderate to severe hepatic impairment, half the recommended daily dose should be used.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Side effects:
Gastrointestinal system: Nausea, gastrointestinal discomfort, increased appetite, and dry mouth, have been reported.
Respiratory system: Thickening of mucous.
Central nervous system: Drowsiness, fatigue, dizziness, headache, anxiety, nervousness, malaise, and asthenia have been reported.
Hypersensitivity reactions: Urticaria, skin rash, pruritus, and angioedema, may develop.

Special precautions:
ALLERMINE Tablets lack significant sedative effects. Patients should be warned, however, that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks, (see "**WARNINGS**"). This effect may be compounded by simultaneous intake of alcohol or other central nervous system depressants (see "**INTERACTIONS**").

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Drowsiness is an expected 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. There is no specific antidote. Cetirizine is not effectively removed by dialysis. FURTHER TREATMENT IS SYMPTOMATIC AND SUPPORTIVE.

IDENTIFICATION:
Film-coated, white, capsule-shaped tablet with a break line on one side.

PRESENTATION:
PVC/Aluminium foil blister strips of 10 tablets, packed in unit cartons of 10 or 30 tablets. White, opaque polypropylene securitainers containing 30 tablets. Amber glass containers containing 30 tablets.

STORAGE INSTRUCTIONS:
Store below 25 °C in well-closed containers, protected from light. Do not remove the blister from the carton until required for use. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
36/5.7.1/0388

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
TRINITY PHARMA (PTY) LTD
3 Gwen Lane, 4th Floor, Sandton, 2031.
Contact No.: +27 (0)10 594 5610
PV Email Address: pv@trinitypharma.co.za

DATE OF PUBLICATION OF THE PACKAGE INSERT:
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TRINITY PHARMA

Tel: 010 594 5610. Email: PV@kahmagroup.co.za

SKELDULERINGSTATUS: S2

HANDELSNAAM (EN DOSEERVORM):

ALLERMINE TABLETS (Filmbedekte tablette)

SAMESTELLING:
Elke filmbedekte tablet bevat 10 mg setirisiendihidrochloried.
Bevat suiker: 74,30 mg laktosemonohidraat.

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.7 .1 Anlihistaminika.

FARMAKOLOGIESE WERKING:
Setirisien is 'n metabo liet van hidroksisien. Dit is 'n tweede-generasie omkeerbare, kompeterende inhibeerder van histamien by die histamien-1 (H1) reseptor. Setirisien kompeteer met histamien vir die H1-reseptor situs. Setirisien verhoed, maar keer nie die farmakologiese response gemedieer deur histamien, by die H1-reseptor om nie.

Farmakokinetika:
Setirisien word goed geabsorbeer uit die gastro'i'ntestina le traktus en piek plasmakonsentrasies word bereik binne 1 uur na orale toediening. Farmakoken ita is line8r, met plasma-konsentrasies wat proporsioneel verhoog met verhoogde dosisse. Die terminale halfleeftyd by volwassenes is ongeveer 10 ure; by kinders 6 tot 12 jaar oud , 6 ure; by kinders 2 tot 6 jaar oud, 5 ure. Setirisien word vinniger uitgeskei by kinders, en stadiger by pasiente met hepatiese of renale inkorting (kreatinienopruiming < 40 ml/min), met 'n gevolglike verhoging in halfleeftyd en vermindering in opruiming. Setirisien ondergaan nie ekstensiewe eerste-deurgang metabolisme nie. Die kumulatiewe urinere uitskeiding verteenwoordig ongeveer twee-derdes van die dosis toegedien by beide volwassenes en kinders.

INDIKASIES:
ALLERMINE Tablets word aangedui vir die simptomatiese verligting van allergiese toestande soos allergiese rinitis, en allergiese vel toestande soos urtikarie.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir enige van die bestanddele. Hipersensitiwiteit vir hidroksisien. Lakterende vrouens, aangesien die aktiewe bestanddeel uitgeskei word in borsmelk. Swangerskap, omdat veiligheid nag nie vasgestel is nie. Kinders ender die ouderdom van twee jaar, aangesien veiligheid en effektiwiteit nag nie bewys is nie.

WAARSKUWINGS :
Hierdie medisyne kan ly tot lomerigheid en belemmerde konsentrasie, wat erger kan word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel depressante middels. Die pasient se vermoe om gevaarlike aktiwiteite te verrig wat verstande like wakkerheid of fisiese kobrdinasie benodig, soos die bestuur of hanteer van masjinerie, kan belemmer word.
Porfirie: Gebruik versigtig.

INTERAKSIES:
Meegaande gebruik van alkoho l en ander kalmerende middels moet vermy word. Daar is geen bewys van 'n interaksie tussen setirisien en simetidien, ketokonasool, eritromisien, asitromisien, diasepam, glipisied en pseudoefedrien nie.

SWANGERSKAP EN LAKTASIE:
Veilighe id gedurende swangerskap en laktasie is nag nie vasgestel nie (sien "**KONTRA-INDIKASIES**").

DOSIS EN GEBRUIKSAAN WYSINGS:
Volwassenes of kinders 12 jaar of ouer: Een 10 mg tab let eenmaal per dag.
Kinders 6 tot 12 jaar oud: Een 10 mg tablet eenmaal per dag of 5 mg (halwe tablet) tweemaal per dag. Geen doseringsaanpassing is nodig by gesonde bejaarde pasiente met normale nierfunksie nie.

Dosering by Renate inkorting:
By pasiente met nierinkorting, waar die kreatinien-opruiming minder is as 40 ml/min, moet die aanbevole daaglikse dosis van setirisien gehalveer word.

Dosering by Hepatiese inkorting:
By matige tot erge hepatiese inkorting, moet die helfte van die aanbevole daaglikse dosis gebruik word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREELS:
Newe-effekte:
Gastroïntestinale stelsel: Naarheid, gastroïntestinale ongemak, verhoogde aptyt, en droe mond, is gerapporteer.
Asemhalingstelsel: Verdikk ing van die mukus.
Sentrale senuweestelsel: Lomerigheid,moegheid, duiseligheid, hoofpyn, angs, senuweeagtigheid, ongesteldheid, en astenie is gerapporteer.
Hipersensitiwiteitsreaksies: Urtikarie, veluitslag, pruritus, en angioedeem kan ontwikkel.

Spesiale voorsorgmaatreël :
ALLERMINE Tablets toon geen beduidende sedatiewe effekte nie. Pasiente moet egter gewaarsku word dat 'n klein aantal individue lomerigheid kan ondervind. Daar word dus aanbeveel om individue le response te bepaal voor die bestuur van 'n voertuig of uitrig van gekompliseerde take (sien "**WAARSKUWINGS**"). Hierd ie effek kan vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel depressante (sien "**INTERAKSIES** ").

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Duiseligheid is 'n simptoom wat verwag kan word. Oordosering by kinders kan opgewondenheid, lomerigheid, pruritus, uitslag, urinere retensie, moegheid, tremor en tagikardie veroorsaak. Ingeval van massiewe oordoser ing, moet gastriese uitspoeling gedoen word saam met die gewone ondersteunende maatreels. Daar is geen spesifieke teenmiddel nie. Setirisien wor d nie effektief verwyder deur dialise nie. VERDERE BEHANDELING IS SIMPTOMA TIES EN ONDERSTEUNEND.

IDENTIFIKASIE:
Filmbedekte, wit, kapsuul-vormige tablet met 'n breeklyn op een kant.

AANBIEDING:
PVC/ Aluminium foelie stolpstrokies met 10 tablette, verpak in eenheid kartonne van 10 of 30 tablette. Wit, ondeurskynende polipropileen securitainers met 30 tablette. Bruin glas houers met 30 tablette.

BERGINGSINSTRUKSIES:
Berg benede 25 °C in diggeslote houers, beskerm teen lig. Moenie die stolpverpakki ng uit die houer haal voor gebruik nie. HOU SUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
36/5.7.1/0388

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:
TRINITY PHARMA (EDMS.) BPK
3 Gwen Lane, 4de vloer, Sandton, 2031.
Kontaknommer: +27 (0)10 594 5610
PV E-posadres: pv@trinitypharma.co.za

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