SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:
LORANO® 10 (tablets)

COMPOSITION:
Each Lorano® 10 tablet contains 10 mg loratadine.
Contains sugar: Lactose.

PHARMACOLOGICAL CLASSIFICATION:
A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:
Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H1-receptor antagonistic activity. Loratadine does not readily cross the blood-brain barrier.
Maximal serum levels were achieved within 1,5 hours. Clinical effect was achieved within 2 hours. Excretion occurred equally via renal and faecal routes.

INDICATIONS:
Loratadine tablets are indicated for the relief of the symptoms associated with seasonal allergic rhinitis and chronic urticaria.

CONTRAINDICATIONS:
Loratadine tablets are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to its components.
Safety of loratadine tablets in the elderly has not been established.
The safe use of loratadine tablets during pregnancy or lactation has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:
Loratadine tablets lack 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.
Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine; an initial dose of 5 mg once daily or 10 mg every second day is recommended.

Lactose intolerance:
LORANO 10 contains lactose, therefore it should not be used by patients with rare hereditary problems of lactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

INTERACTIONS:
Loratadine tablets should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Loratadine is metabolised by cytochrome P450 isoenzymes CYP3A4 and CYP2D6. Concomitant administration of other drugs that inhibit or are metabolised by these hepatic enzymes may result in changes in the plasma concentrations of either drug and, possibly may have adverse effects.

Cimetidine, erythromycin, ketoconazole, quinidine, fluconazole and fluoxetine are all known to inhibit one or other of these enzymes.

Erythromycin, ketoconazole and cimetidine are all known to inhibit the metabolism of loratadine.

Similarly clarithromycin inhibits the metabolism of loratadine and its active metabolite descarboethoxyloratadine.

PREGNANCY AND LACTATION:
The safe use of loratadine tablets during pregnancy or lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
Adults:
One LORANO tablet once daily.

SIDE EFFECTS:
Most commonly reported side effects include fatigue, headache, somnolence, dry mouth, gastro-intestinal disorders such as nausea, gastritis and also allergic symptoms like rash.
Alopecia, anaphylaxis and abnormal hepatic function have been reported rarely.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Refer to “Side effects, Warnings and special precautions”.

Overdosage information:
Somnolence, tachycardia and headache have been reported with overdoses. In the event of overdosage, treatment should be started immediately.

Treatment:
Treatment is symptomatic and supportive. Loratadine is not cleared by haemodialysis to any appreciable extent.

IDENTIFICATION:
The Lorano® 10 tablets are white, oval, notch and code LT/10 on one side.
Length: 7,5 to 7,9 mm
Width: 4,9 to 5,3 mm

PRESENTATION:
The tablets are packed into white, opaque PVC/aluminium blister strips containing 10 tablets each.
1 (10) blister strips packed into a carton i.e. 10 tablets per carton.
3 (10) blister strips packed into a carton i.e. 30 tablets per carton.
25 (10) blister strips packed into a carton i.e. 250 tablets per carton.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from excessive moisture.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
35/5.7.1/0354

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Trinity Pharma (Pty) Ltd[1]
106 16th Road,
Building 2, Midrand
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
Last approval date: 15 November 2002
Date compliant with regulation 9 & 10: 15 February 2016

TRINITY PHARMA

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

SKEDULERINGSTATUS: S2

HANDELSNAAM EN DOSEERVORM:
LORANO® 10 (tablette)

SAMESTELLING:
Elke Lorano® 10 tablet bevat 10 mg loratadien.
Bevat lactose.

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.7.1 Antihistaminika

FARMAKOLOGIESE WERKING:
Loratadien is ’n langwerkende, tri-sikliese antihistamien met selektiewe periferiese H1-reseptor antagonistiese werking.
Loratadien kruis nie maklik die bloedbreinkans nie.
Maksimale serumvlakke is binne 1,5 ure bereik. Kliniese effek is
binne 2 ure bereik. Uitskeiding vind in gelyke mate plaas via renale en fekale roetes.

INDIKASIES:
Loratadien tablette word aangedui vir die verligting van die simptome geassosieer met seisoenale allergiese rinitis en chroniese urtikaria (netelroos).

KONTRA-INDIKASIES:
Loratadien tablette is teenaangedui in pasiënte wat hipersensitiwiteit of idiosinkrasie tot die komponente getoon het.
Die veiligheid van loratadien tablette vir bejaardes is nog nie vasgestel nie.
Die veilige gebruik van loratadien tablette gedurende swangerskap of borsvoeding is nog nie vasgestel nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Loratadien tablette het ’n gebrek aan beduidende sedatiewe gevolge. Pasiënte moet egter gewaarsku word dat ’n klein aantal individue sedasie mag ervaar. Dit is daarom raadsaam om individuele reaksie te bepaal voordat bestuur word of ingewikkelde take uitgevoer word. Hierdie effek mag vererger word deur die gelyktydige inname van alkohol of ander sentrale senustelselonderdrukkers.
’n Laer aanvangsdosis moet aan pasiënte met ernstige leweraantasting toegedien word omdat hulle verminderde opruiming van loratadien mag hê; ’n aanvangsdosis van 5 mg een keer per dag of 10 mg elke tweede dag word aanbeveel.

INTERAKSIES:
Loratadien tablette moet ongeveer 48 uur voor ’n veltoetsprosedure gestaak word aangesien antihistamiene andersins positiewe reaksies op indikators van dermale reaksievermoë mag verhoed of verminder.

Loratadien word deur sitochroom P450 isoënsieme CYP3A4 en CYP2D6 gemetaboliseer. Gelyktydige toediening van ander geneesmiddels wat hierdie hepatiese ensieme rem of deur hulle gemetaboliseer word, kan tot veranderinge in die plasmakonsentrasies van enige van die geneesmiddels lei en kan moontlike nadelige gevolge hê.

Simetidien, eritromisien, ketokonasool, kinidien, flukonasool en fluoksetien is almal daarvoor bekend om een van hierdie ensieme te rem.

Eritromisien, ketokonasool en simetidien is almal daarvoor bekend dat hulle die metobolisering van loratadien rem.
Net so, rem klaritromisien die metabolisering van loratadien en sy aktiewe metaboliet deskarboëtoksie loratadien.

SWANGERSKAP EN BORSVOEDING:
Die veilige gebruik van loratadien tablette gedurende swangerskap of laktasie is nog nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes:
Een LORANO 10 tablet een keer per dag.

NEWE-EFFEKTE:
Die mees algemeen aangemelde newe-effekte sluit in moegheid, hoofpyn, slaperigheid, droë mond, gastroïntestinale aandoenings soos naarheid, gastritis en ook allergiese simptome soos uitslag. Alopesie, anafilakse en abnormale hepatiese funksie is selde aangemeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Verwys na “**NEWE EFFEKTE”, “WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS”.**

Inligting oor oordosering:
Slaperigheid, tagikardie en hoofpyn is aangemeld met oordosering.
In geval van oordosering moet behandeling onmiddellik begin word.

Behandeling:
Behandeling is simptomaties en ondersteunend. Loratadien word nie tot enige bevredigende mate deur hemodialise opgeruim nie.

IDENTIFIKASIE:
Die Lorano® 10 tablette is wit, ovaal, gekeep en kode LT/10 aan een kant.
Lengte: 7,5 to 7,9 mm
Breedte: 4,9 to 5,3 mm

AANBIEDINGE:
Die Lorano® 10 tablette is verpak in wit, ondeurskynende PVC/ aluminium stulpstroke wat elk 10 tablette bevat.
1 (10) stulpstroke verpak in ’n kartondosie, d.i. 10 tablette per kartondosie.
3 (10) stulpstroke verpak in ’n kartondosie, d.i. 30 tablette per kartondosie.
25 (10) stulpstroke verpak in ’n kartondosie, d.i. 250 tablette per kartondosie.

BERGINGSINSTRUKSIES:
Bewaar teen of onder 25 °C. Beskerm teen oormatige vog.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
35/5.7.1/0354

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Trinity Pharma (Pty) Ltd[1]
106 16th Weg,
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Suid Afika

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