SCHEDULING STATUS:
S1

PROPRIETARY NAME AND DOSAGE FORM:
LORATADINE 10 BIOTECH (tablets)

COMPOSITION:
Each LORATADINE 10 BIOTECH tablet contains 10 mg loratadine.
Excipients: Colloidal anhydrous silica, magnesium stearate and maize starch.
Contains sugar: lactose monohydrate 69,1 mg.

PHARMACOLOGICAL CLASSIFICATION:
A.5.7.1 Antihistaminic

PHARMACOLOGICAL ACTION:
Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H_1 –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 10 BIOTECH tablets are indicated for the relief of the symptoms associated with seasonal allergic rhinitis and chronic urticaria.

CONTRAINDICATIONS:
LORATADINE 10 BIOTECH tablets are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to loratadine or to any of the ingredients of LORATADINE 10 BIOTECH.
Safety of LORATADINE 10 BIOTECH tablets in the elderly has not been established.
The safe use of LORATADINE 10 BIOTECH tablets during pregnancy or lactation has not been established (See PREGNANCY AND LACTATION).

WARNINGS AND SPECIAL PRECAUTIONS:
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.
Effects on the ability to drive and use machines:
LORATADINE 10 BIOTECH 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. The effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.
LORATADINE 10 BIOTECH contains lactose. Patients with rare hereditary conditions of galactose intolerance, e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption should not take LORATADINE 10 BIOTECH.

INTERACTIONS:
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 well 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.
LORATADINE 10 BIOTECH 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.

PREGNANCY AND LACTATION:
The safe use of LORATADINE 10 BIOTECH tablets during pregnancy or lactation has not been established (See CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE:
Adults:
One LORATADINE 10 BIOTECH 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:
(See SIDE EFFECTS).
Overdosage Information:
Somnolence, tachycardia and headache have been reported with overdose. 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:
LORATADINE 10 BIOTECH are white, oval tablets, notched and coded LT/10 on one side.
Length: 7,5 to 7,9 mm
Width: 4,9 to 5,3 mm

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

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

REGISTRATION NUMBER:
35/5.7.1/0355

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
Date of registration: November 2002
Date of notification with regard to amended Reg. 9 and 10:
07 July 2017

PIA350355/2

SKEDULERINGSTATUS:
S1

EIENDOMSNAAM EN DOSEERVORM:
LORATADINE 10 BIOTECH (tablette)

SAMESTELLING:
Elke LORATADINE 10 BIOTECH tablet bevat 10 mg loratadien.
Onaktiewe: Kolloïdale anhidriese silika, magnesiumstearaat en mieliestysel.
Bevat suiker: laktosemonohidraat 69,1 mg.

FARMAKOLOGIESE KLASSIFIKASIE:
A.5.7.1 Antihistamiene

FARMAKOLOGIESE WERKING:
Loratadien is 'n lang-werkende, trisikliese antihistamien met 'n selektiewe perifere H_1 –reseptor-antagonistiese aktiwiteit. Loratadien kruis nie maklik die bloed-breinskans nie.
Maksimum serumvlakke is binne 1,5 uur behaal. Kliniese effek word binne 2 uur behaal. Uitskeiding vind terselfdertyd plaas deur die nier- en fekale roetes.

INDIKASIES:
LORATADINE 10 BIOTECH tablette word aangedui vir die verligting van simptome geassosieer met seisoenale allergiese rinitis en chroniese urtikaria.

KONTRAINDIKASIES:
LORATADINE 10 BIOTECH tablette word gekontraïndikeer in pasiënte wat 'n hipersensitiwiteit of onverdraagsaamheid het teenoor loratadien of enige van die bestanddele van LORATADINE 10 BIOTECH.
Die veiligheid van gebruik van LORATADINE 10 BIOTECH tablette onder bejaardes is nog nie vasgestel nie.
Die veilige gebruik van LORATADINE 10 BIOTECH tablette gedurende swangerskap of laktasie is nog nie vasgestel nie (Sien SWANGERSKAP EN LAKTASIE).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Pasiënte met erge lewerbelemmering moet 'n laer aanvanklike dosis toegedien word, aangesien dit die vrystelling van loratadien kan verminder; 'n aanvanklike dosis van 5 mg een maal daagliks of 10 mg elke tweede dag word aanbeveel.
Uitwerking op die vermoë om te bestuur en die gebruik van masjinerie:
LORATADINE 10 BIOTECH tablette het nie 'n beduidende sederende effek nie. Pasiënte moet egter gewaarsku word dat 'n klein aantal individue sedasie of verlies van konsentrasie kan ervaar. Dit is dus raadsaam om individuele reaksie te bepaal voordat u bestuur of ingewikkelde take uitvoer.
Slaperigheid en belemmerde konsentrasie kan vererger word deur die gelyktydige inname van alkohol of ander senuweestelsel depressante.
LORATADINE 10 BIOTECH bevat laktose. Pasiënte met seldsame oorerflike toestande van galaktose-intoleransie, bv. Galaktosemie, Lapp laktase tekort, glukose-galaktose wanabsorpsie moet nie LORATADINE 10 BIOTECH neem nie.

INTERAKSIES:
Loratadine word gemetaboliseer deur die sitochroom P450 isoensiem CYP3A4 en CYP2D6. Gelyktydige toediening van ander middels wat deur hierdie hepatiese ensieme inhibeer of gemetaboliseer word, kan veranderinge in die plasmakonsentrasies van enige geneesmiddel tot gevolg hê en kan moontlik nadelige gevolge hê.
Simetidien, eritromisien, ketokonasool, kinidien, flukonasool en fluoksetien is almal bekend daarvoor om van hierdie ensieme te inhibeer.
Eritromisien, ketokonasool en simetidien is almal bekend daarvoor om die metabolisme van loratadien te inhibeer.
Op dieselfde wyse inhibeer klaritromisien die metabolisme van loratadien en sy aktiewe metaboliet deskarboetoksiloratadien.
LORATADINE 10 BIOTECH tablette moet ongeveer 48 uur voor veltoetsprosedures gestaak word, aangesien antihistamiene andersins positiewe reaksies op dermale reaktiwiteitsaanwysers kan voorkom of verlaag.

SWANGERSKAP EN LAKTASIE:
Die veilige gebruik van LORATADINE 10 BIOTECH tablette gedurende swangerskap of laktasie is nog nie vasgestel nie (Sien KONTRAÏNDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes:
Een LORATADINE 10 BIOTECH tablet een maal per dag.

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

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:
(Sien NEWE EFFEKTE).
Simptome van oordosering:
Slaperigheid, tagikardie en hoofpyn is aangemeld met 'n oordosis.
In die geval van oordosering moet die behandeling van oordosering onmiddellik begin word.
Behandeling van oordosering:
Behandeling is simptomaties en ondersteunend van aard. Loratadien word in geen noemenswaardige mate deur hemodialise ontruim nie.

IDENTIFIKASIE:
LORATADINE 10 BIOTECH is 'n wit, ovaal tablet, wat ingekeep en gekodeer is met LT/10 aan die een kant.
Lengte: 7,5 tot 7,9 mm
Wydte: 4,9 tot 5,3 mm

AANBIEDING:
LORATADINE 10 BIOTECH tablette word verpak in wit, ondeursigtige PVC / aluminium stulpstroke van 10 tablette elk.
1 (10) stulpstrook verpak in 'n karton d.w.s 10 tablette per karton.
3 (10) stulpstroke verpak in 'n karton d.w.s 30 tablette per karton.

BERGINGSAANWYSINGS:
Bewaar teen of benede 25 °C. Beskerm teen oormatige vog.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
35/5.7.1/0355

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Biotech Laboratories (Edms) Bpk.
Grond Vloer, Blok K Wes, Central Park
16de Weg 400, Randjespark, Midrand, 1685
Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie: November 2002
Datum van kennisgewing met betrekking tot wysiging - Reg. 9 en 10: 07 Julie 2017

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