PACKAGE INSERT FOR DESOTAB

SCHEDULING STATUS:
S2

PROPRIETARY NAME (and dosage form):
DESOTAB (tablets)

COMPOSITION:
Each **DESOTAB** tablet contains 5 mg desloratadine.

PHARMACOLOGICAL CLASSIFICATION:
A 5.7.1 Antihistaminic

PHARMACOLOGICAL ACTION:
Desloratadine is the major, long acting, active metabolite of loratadine, a non-sedating second-generation H_1 antagonist. It blocks peripheral histamine H_1 receptors since it crosses the blood-brain barrier to a limited extent. Except for its antihistaminic activity, studies also indicated inhibition of events leading to allergic-inflammation.

Pharmacokinetics
Desloratadine is rapidly absorbed from the gastrointestinal tract and reaches maximum plasma concentrations in 3 hours. There is no evidence of drug accumulation and food has no influence on the absorption of desloratadine. The percentage desloratadine bound to plasma proteins is an average of 85 %. The mean elimination half-life for desloratadine is 28 hours.

INDICATIONS:
DESOTAB is indicated for the relief of symptoms associated with seasonal allergic rhinitis.

CONTRAINDICATIONS:
Hypersensitivity to desloratadine or to any ingredients of this preparation.
Cross sensitivity to other antihistamines.
Safety during pregnancy and lactation has not been established (see **PREGNANCY AND LACTATION**).
Porphyria.

WARNINGS:
Safety of **DESOTAB** in the elderly has not been established.
Safety of **DESOTAB** in children under two years of age has not been established.

DESOTAB should be used with caution in patients with:
- Severe liver impairment, as reduced clearance of desloratadine may occur.
  Dosage adjustment may be needed (see **DOSAGE AND DIRECTIONS FOR USE**).
- Renal impairment - A lower starting dose should be used. In patients with chronic renal impairment (creatinine clearance of 30 ml/minute or less), both oral bioavailability and peak plasma concentrations of desloratadine may be increased.

DESOTAB lacks significant sedative effects, although some patients may still experience drowsiness.

INTERACTIONS:
Concomitant use of **DESOTAB** with inhibitors of cytochrome P450 enzyme system such as cimetidine, ketoconazole, clarithromycin and erythromycin may increase the plasma concentration of desloratadine (an increase in the C_{max} and in the AUC).
Dosage adjustments should be considered.

PREGNANCY AND LACTATION:
Safety and efficacy in pregnancy and lactation have not been established.
Desloratadine has been detected in breast milk. Small amounts of desloratadine entering breast milk may cause drowsiness or excitability in the infants.

DOSAGE AND DIRECTIONS FOR USE:
Adults and adolescents (≥ 12 years):
One tablet orally, once daily.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
SIDE-EFFECTS:
Central nervous system:

Frequent:	Headache
Less frequent:	Fatigue, somnolence, sedation, nervousness, blurred vision, confusion and nightmares

Gastro-intestinal:

Frequent:	Dry mouth, gastro-intestinal disorders such as nausea and gastritis

Liver:

Less frequent:	Abnormal hepatic function

Skin:

Frequency unknown:	Rash, alopecia

Other:

Less frequent:	Allergic reactions
Frequency unknown:	Anaphylaxis

SPECIAL PRECAUTIONS:
DESOTAB should be discontinued prior to skin tests with allergen extracts as it may inhibit the cutaneous histamine response, thus producing false-negative results.
DESOTAB should be discontinued at least 48 hours before test.
DESOTAB should be used with caution when the following medical caution exists and/or patients using other medication metabolised by the cytochrome P450 system:
- Emphysema; prostatic hypertrophy; narrow angle glaucoma; cardiovascular disorder; epilepsy or during acute attacks of asthma.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See **SIDE-EFFECTS AND SPECIAL PRECAUTIONS).**
Symptoms of overdose:
Somnolence, tachycardia and headaches have been reported. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment of overdose:
Treatment is symptomatic and supportive. After overdose of **DESOTAB**, the stomach should be emptied immediately by inducing emesis or by gastric lavage. Administration of activated charcoal after emesis may be useful in preventing absorption of **DESOTAB.** Saline cathartics may be of value to rapidly dilute bowel contents. **DESOTAB** is not cleared by haemodialysis.

IDENTIFICATION:
DESOTAB are orange coloured, round, flat, uncoated tablets with breakline on one side and plain on the other. The tablets should be free of all physical defects.

PRESENTATION:
DESOTAB tablets are packed in an aluminium/aluminium foil strip pack containing ten tablets. One or three strips are packed in an outer carton.

STORAGE INSTRUCTIONS:
Store at or below 25 °C.
Protect from light.
Keep blisters in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
A41/5.7.1/0226

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Zydus Healthcare S.A. (Pty) Ltd.
Adrina Building, First Floor
32-34 Klinkenberg Street
Potchefstroom, 2531

MARKETED BY:
Forrester Pharma (Pty) Ltd
13 Pasita Street
Rosen Heights
Rosen Park
Bellville, 7530

DATE OF PUBLICATION OF THE PACKAGE INSERT:
November 2007

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FORRESTER PHARMA

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before taking DESOTAB.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling status: Schedule 2

Proprietary name, strength and pharmaceutical form:
DESOTAB (each tablet contains 5 mg desloratadine).

1. WHAT DESOTAB CONTAINS
- The active substance is desloratadine.
- The other inactive ingredients: methacrylic acid polymer with divinyl benzene and acrylic acid (Indion 204 I.H), purified water, mannitol, croscarmellose sodium, flavour Trusil mango special I.H, aspartame, Sunset Yellow lake I.H, colloidal silicon dioxide, sodium stearyl fumarate.

2. WHAT DESOTAB IS USED FOR
DESOTAB is indicated for the relief of symptoms associated with seasonal allergic rhinitis (sneezing, rhinorrhoea and itching of the eyes, nose and throat).

3. BEFORE YOU TAKE DESOTAB
Do not take DESOTAB:
- If you are hypersensitive (allergic) to desloratadine or any of the ingredients (see "**What DESOTAB contains**").
- If you are pregnant or breastfeeding your baby.

Take special care with DESOTAB:
Inform your doctor if you are suffering from liver function impairment, as the dosage you should take may need to be adjusted.

Elderly patients are more likely to have age related impairment of the liver or kidney function, which may require adjustment of dosage in patients receiving **DESOTAB**.

Pregnancy and breastfeeding:
DESOTAB should not be used if you are pregnant or breastfeeding your baby. Please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:
DESOTAB has no effect on the ability to drive and use machines.

Using other medicines with DESOTAB:
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **DESOTAB** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop.

Medicines known to influence the effect of desloratadine are anti-fungal (ketoconazole) and antibiotic (erythromycin) treatment.

4. HOW TO USE DESOTAB
Adults (≥ 12 years of age): One tablet orally, once daily.

If you take more DESOTAB than you should:
In event of overdosage, consult your doctor of pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take DESOTAB:
If you forget to take a dose, take it as soon as you remember. Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

5. POSSIBLE SIDE-EFFECTS
DESOTAB can have side-effects. Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following occur, tell your doctor immediately since it may indicate a need for medical attention:
- Anaphylaxis (cough; difficulty swallowing; dizziness; fast heartbeat; hives; itching; puffiness or swelling of the eyelids, face, lips or tongue; shortness of breath; skin rash; tightness in chest and wheezing).
- Dyspnoea (shortness of breath).

The above-mentioned are all serious side-effects and the frequency has not been determined.

The following side-effects may also require medical attention.
The frequency of occurrence has not been determined.
- Swelling of legs and ankles
- Itching and redness skin, hives or welts, and skin rash
- Fast, pounding or irregular heartbeat or pulse

Side-effects that require medical attention only if they become bothersome are the following

Frequent occurrence:	Headache and pharyngitis (body aches or pain, congestion, cough, hoarseness, runny nose).
Less frequent occurrence:	Dizziness, dry mouth, difficult or painful menstruation, acid or sour stomach, unusual tiredness or weakness, muscle aching or cramping, nausea.

If you notice any side-effect not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF DESOTAB
- Store at or below 25 °C.
- Protect from light.
- Blisters must be kept in the outer carton until required for use.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use the tablets after the expiry date printed on the blisters and containers. Decomposed products may be toxic.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF DESOTAB
DESOTAB is packed in an aluminium/aluminium foil strip pack containing ten tablets. One or three strips are packed in an outer carton.

8. IDENTIFICATION OF DESOTAB
DESOTAB are orange coloured, round, flat, uncoated tablets with breakline on one side and plain on the other. The tablets should be free of all physical defects.

9. REGISTRATION NUMBER
A41/5.7.1/0226

NAME AND ADDRESS OF THE REGISTRATION HOLDER
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FORRESTER PHARMA

VOUBILJET VIR DESOTAB
SKEDULERINGSTATUS:
S2

EIENDOMSNAAM (en doseervorm):
DESOTAB (tablette)

SAMESTELLING:
Elke **DESOTAB** tablet bevat 5 mg desloratadien.

FARMAKOLOGIESE KLASSIFIKASIE:
A 5.7.1 Antihistaminika

FARMAKOLOGIESE WERKING:
Desloratadien is die hoof, langwerkende, aktiewe metaboliet van loratadien, 'n nie-sederende tweedegenerasie H_1-antagonis. Dit blokkeer perifere histamien H_1-reseptore, aangesien dit die bloedbreinskans in 'n beperkte mate kruis. Buiten die antihistamienwerking daarvan, het studies ook aangedui dat voorvalle wat lei tot allergiese inflammasie, geïnhibeer word.

Farmakokinetiese eienskappe:
Desloratadien word vinnig uit die gastro-intestinale weg geabsorbeer en bereik maksimum plasmakonsentrasie binne 3 uur. Daar is geen aanduiding van geneesmiddelopeenhoping nie en kos het geen uitwerking op die absorpsie van desloratadien nie. Die persentasie desloratadien wat aan plasmaproteïen gebind is, is gemiddeld 85 %. Die gemiddelde eliminasiehalfleeftyd vir desloratadien is 28 uur.

INDIKASIES:
DESOTAB word aangedui vir die verligting van simptome wat geassosieer word met seisoenale allergiese rinitis.

KONTRA-INDIKASIES:
Hipersensitiwiteit vir desloratadien of vir enige van die bestanddele van hierdie formule.
Kruissensitiwiteit vir ander antihistamiene.
Veiligheid gedurende swangerskap en borsvoeding is nie bepaal nie (sien **SWANGERSKAP EN BORSVOEDING**).
Porfirie.

WAARSKUWINGS:
Die veiligheid van **DESOTAB** by bejaardes, is nie bepaal nie.
Die veiligheid van **DESOTAB** by kinders jonger as twee jaar, is nie bepaal nie.

DESOTAB moet versigtig gebruik word by pasiënte met:
- Erge lewerbelemmering, aangesien verminderde opruiming van desloratadien mag voorkom. Dit mag nodig wees om die dosis aan te pas (sien **DOSIS EN GEBRUIKSAANWYSINGS**).
- Renale inkorting – 'n Laer aanvangsdosis moet gebruik word. By pasiënte met chroniese renale belemmering (kreatinienopruiming van 30 ml/minuut of minder), mag sowel orale biobeskikbaarheid as piekplasmakonsentrasies van desloratadien verhoog wees.

DESOTAB het nie beduidende sederende effekte nie, alhoewel sommige pasiënte steeds lomerig kan word.

INTERAKSIES:
Die gelyktydige gebruik van **DESOTAB** saam met inhibitore van die sitochroom P450-ensiemsisteem, soos simetidien, ketokonasool, klaritromisien en eritromisien, mag die plasmakonsentrasie van desloratadien verhoog ('n toename in die C_{maks} en in die AOK). Dosisaanpassings moet oorweeg word.

SWANGERSKAP EN BORSVOEDING:
Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie. Desloratadien is in borsmelk waargeneem. Klein hoeveelhede van desloratadien wat in die borsmelk voorkom, mag lomerigheid of prikkelbaarheid by die baba veroorsaak.

DOSIS EN GEBRUIKSAANWYSINGS:
Volwassenes en adolessente (≥ 12 jaar):
Een tablet per mond geneem, een keer daagliks.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
NEWE-EFFEKTE:
Sentrale senuweestelsel:
Dikwels: Hoofpyn
Minder dikwels: Uitputting, slaperigheid, sedasie, senuweeagtigheid, wasige visie, verwarring en nagmerries

Gastro-intestinaal:
Dikwels: Droë mond, gastro-intestinale versteurings soos naarheid en gastritis

Lewer:
Minder dikwels: Abnormale lewerfunksie

Vel:
Frekwensie onbekend: Veluitslag, alopesie

Ander:
Minder dikwels: Allergiese reaksies
Frekwensie onbekend: Anafilakse

SPESIALE VOORSORGMAATREËLS:
DESOTAB moet gestaak word voor veltoetse met allergeenekstrakte uitgevoer word, aangesien dit die kutane histamienrespons mag inhibeer en sodoende vals-negatiewe resultate kan veroorsaak.
DESOTAB moet ten minste 48 uur voor die toets uitgevoer word, gestaak word.
DESOTAB moet met oorleg gebruik word wanneer die volgende mediese toestande teenwoordig is en/of pasiënte ander medikasie gebruik wat deur die sitochroom P450-sisteem gemetaboliseer word:
- Emfiseem; prostaathipertrofie; nou-hoekgloukoom; kardiovaskulêre versteuring; epilepsie of gedurende akute asma-aanvalle.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:
(sien **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**).
Simptome van oordosering:
Slaperigheid, tagikardie en hoofpyne is aangemeld. Ekstrapiramidale manifestasies en palpitasies is by kinders aangemeld.

Behandeling van oordosering:
Behandeling is simptomaties en ondersteunend. Na oordosering met **DESOTAB**, moet die maag onmiddellik geledig word deur emese te induseer of deur gastriese spoeling. Toediening van geaktiveerde houtskool na emese mag nuttig wees in die voorkoming van absorpsie van **DESOTAB**.
'n Purgeermiddel van fisiologiese soutoplossing kan help om die derminhoud vinnig te verdun. **DESOTAB** word nie deur hemodialise verwyder nie.

IDENTIFIKASIE:
DESOTAB is oranjekleurige, ronde, plat, onbedekte tablette met 'n breeklyn aan die een kant en skoon aan die anderkant. Die tablette moet sonder enige fisiese defekte wees.

AANBIEDING:
DESOTAB tablette word verpak in 'n aluminium/aluminiumfoeliestrook, wat tien tablette bevat. Een of drie stroke word in 'n buitenste karton verpak.

BEWARINGSINSTRUKSIES:
Bêre by of onder 25 °C.
Beskerm teen lig.
Hou die stulpstroke in die buitenste verpakking tot benodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
A41/5.7.1/0226

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Zydus Healthcare S.A. (Edms) Bpk.
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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
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PASIËNTINLIGTINGSBLAD

Lees asseblief hierdie inligtingsblad noukeurig deur, voordat DESOTAB geneem word.
- Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Indien u verdere vrae het, kontak asseblief u dokter of apteker.
- Hierdie medisyne is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al het hulle dieselfde simptome as u.

Skeduleringstatus: Skedule 2

Eiendomsnaam, sterkte en farmaseutiese vorm:
DESOTAB (elke tablet bevat 5 mg desloratadien).

1. WAT DESOTAB BEVAT
- Die aktiewe bestanddeel is desloratadine.
- Die onaktiewe bestanddele is: metakrielsuurpolimeer met divinielbenseen en akrielsuur (Indion 204 I.H), gesuiwerde water, mannitol, natriumkruiskarmellose, Trusil "mango special" I.H geurmiddel, aspartaam, Sunset Yellow lake I.H, kolloïdale silikondioksied, natriumstearielfumaraat.

2. WAARVOOR DESOTAB GEBRUIK WORD
DESOTAB word aangedui vir die verligting van simptome geassosieer met seisoenale allergiese rinitis (nies, loopneus en jeukende oë, neus en keel).

3. VOORDAT U DESOTAB NEEM
Moet nie DESOTAB neem nie:
- Indien u hipersensitief (allergies) is vir desloratadien of enige van die bestanddele (sien **"WAT DESOTAB BEVAT"**).
- Indien u swanger is of u baba borsvoed.

Wees baie versigtig met DESOTAB:
Lig u dokter in indien u aan belemmerde lewerfunksie ly, aangesien dit nodig mag wees om die dosis wat u moet neem aan te pas.

Dit is meer waarskynlik dat bejaarde pasiënte ouderdomsverwante belemmering van lewer- of nierfunksie het, wat dosisaanpassing nodig kan maak in pasiënte wat **DESOTAB** ontvang.

Swangerskap en borsvoeding:
DESOTAB moet nie gebruik word indien u swanger is of u baba borsvoed nie. Konsulteer asseblief u dokter, apteker of ander gesondheidsorgdeskundige.

Bestuur en gebruik van masjinerie:
DESOTAB het geen uitwerking op die vermoë om te bestuur en masjinerie te gebruik nie.

Die gebruik van ander medisyne saam met DESOTAB:
Indien u ander medisyne op 'n gereelde basis gebruik, insluitende aanvullende of tradisionele medisyne, mag die gebruik van **DESOTAB** saam met hierdie medisyne ongewenste interaksies tot gevolg hê.

Raadpleeg u dokter, apteker of ander gesondheidsorgdeskundige vir advies. Lig u dokter of apteker in indien u enige ander medisyne gebruik, insluitende enige wat u by die apteek, supermark of gesondheidskoswinkel gekoop het.

Medisynes wat bekend is dat dit die uitwerking van desloratadien beïnvloed, is antiswammiddels (ketokonasool) en antibiotiese (eritromisien) behandeling.

4. HOE OM DESOTAB TE GEBRUIK
Volwassenes (≥ 12-jarige ouderdom):
Een tablet per mond geneem, een keer daagliks.

Indien u meer DESOTAB geneem het as wat u behoort:
In geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, verkry hulp by die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om DESOTAB te neem:
Indien u vergeet om 'n dosis te neem, neem dit sodra u onthou. Moet nie 'n dubbele of groter dosis neem om te vergoed vir die vergete individuele dosisse nie. Gaan voort om die volgende tablet op die gewone tyd te neem.

Indien u sukkel om te onthou wanneer om u medisyne te neem, vra u apteker vir wenke in die verband.

5. MOONTLIKE NEWE-EFFEKTE
DESOTAB kan newe-effekte hê. Nie al die newe-effekte wat vir hierdie medisyne aangemeld is, word in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid verswak terwyl hierdie medisyne geneem word, konsulteer asseblief u dokter, apteker of ander gesondheidsorgdeskundige.

Indien enige van die volgende voorkom, sê onmiddellik vir u dokter aangesien dit mag aandui dat u mediese sorg benodig:
- Anafilakse (hoes; sukkel om te sluk; duiseligheid; vinnige hartklop; galbulte; gejeuk; pofferigheid of swelling van die ooglede, gesig, lippe of tong; kortasemheid; veluitslag; stywe gevoel in borskas en gehyg.
- Dispnee (kortasemheid).

Bogenoemde is alles ernstige newe-effekte en die frekwensie is nie bepaal nie.

Die volgende newe-effekte mag ook mediese aandag vereis.
Die frekwensie van voorkoms is nie bepaal nie.
- Swelling van die bene en enkels
- Gejeuk en rooiheid van die vel, galbulte of bort, en veluitslag
- Vinnige, harde of onreëlmatige hartklop of pols

Newe-effekte wat slegs mediese aandag vereis indien dit lastig raak, is die volgende:
Kom dikwels voor: Hoofpyn en faringitis (lyfseer of pyn, kongestie, hoes, heesheid, loopneus).
Kom minder dikwels voor: Duiseligheid, droë mond, moeilike of pynlike menstruasie, suurmaag, ongewone moegheid of swakheid, spiere wat seer is of kramp, naarheid.

Indien u enige newe-effek opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

6. BERGING EN WEGDOENING VAN DESOTAB
- Bêre by of onder 25 °C.
- Beskerm teen lig.
- Hou die stulpstroke in die buitenste karton tot benodig vir gebruik.
- BÊRE ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
- Moenie die tablette ná die vervaldatum wat op die stulpstroke en houers gedruk is, gebruik nie. Produkte wat ontbind het, mag giftig wees.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

7. AANBIEDING VAN DESOTAB
DESOTAB word verpak in 'n aluminium/aluminiumfoeliestrook, wat tien tablette bevat. Een of drie stroke word in 'n buitenste karton verpak.

8. IDENTIFIKASIE VAN DESOTAB
DESOTAB is oranjekleurige, ronde, plat, onbedekte tablette met 'n breeklyn aan die een kant en skoon aan die ander kant. Die tablette moet sonder enige fisiese defekte wees.

REGISTRASIENOMMER
A41/5.7.1/0226

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