V4 (15.02.2016)	***Most recent MCC approval date: 21 May 2012***	***Date Submitted: 15 February 2016***
APPLICANT:	Sandoz SA (Pty) Ltd	
PROPRIETARY NAME (DOSAGE FORM):	LORANO 10 (tablets)	
REGISTRATION NUMBER:	35/5.7.1/0354	

PROPOSED PACKAGE INSERT

SCHEDULING STATUS: S2

PROPRIETARY NAME AND DOSAGE FORM:

LORANO® 10 (tablets)

COMPOSITION:

Each Lorano® 10 tablet contains 10 mg loratadine.

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.

CONTRA-INDICATIONS:

Loratadine tablets are contra-indicated 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.

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:

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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:

Sandoz SA (Pty) Ltd[1]

72 Steel Road

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Spartan

Kempton Park

1619

South Africa

Additional countries registration details:

Country	***Product name***	***Scheduling status (or Category of distribution)***	***Registration number***
Namibia	LORANO	NS1	05/5.7.1/0181
Zambia	LORANO	POM	039/061

ATC Code:
R06AX13 - Other antihistamines for systemic use

Name and address of manufacturer:
Salutas Pharma GmbH
Otto–von–Guericke allee 1
Barleben
Germany

[1] Company Reg. No.: 1990/001979/07

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

Last approval date: 15 November 2002

Date compliant with regulation 9 & 10: 15 February 2016