Professional Information

SCHEDULING STATUS:

S1

PROPRIETARY NAME AND DOSAGE FORM:

DEMAZIN ONCE A DAY tablets

COMPOSITION:

Each tablet contains loratadine 10 mg

PHARMACOLOGICAL CLASSIFICATION:

A 5.7.1 Antihistaminics

PHARMACOLOGICAL ACTION:

Loratadine is a second generation histamine (H1)-receptor antagonist. Loratadine exerts its action by competing with histamine for H1-receptor sites on effector cells. It prevents, but does not reverse responses mediated by histamine. Loratadine does not cross the blood brain barrier to any extent.

Pharmacokinetics:

After oral administration, loratadine is well absorbed from the gastrointestinal tract and peak plasma concentrations are reached within 1,5 hours. Ingestion of food may enhance the absorption of loratadine. Loratadine undergoes extensive first pass metabolism via the cytochrome P-450 system. The major metabolite, desloratadine, is active. Loratadine is 97% protein bound, while desloratadine is less extensively protein bound (73 % to 77 %). The mean elimination half-lives for loratadine and desloratadine are 8,4 and 28 hours, respectively.

INDICATIONS:

DEMAZIN ONCE A DAY is indicated for the relief of the symptoms associated with seasonal allergic rhinitis and chronic urticaria.

CONTRA-INDICATIONS:

Hypersensitivity to DEMAZIN ONCE A DAY or any of the ingredients. Cross sensitivity to other antihistamines. Porphyria.

WARNINGS:

Safety of DEMAZIN ONCE A DAY in the elderly has not been established.

Safety of DEMAZIN ONCE A DAY in children under two years of age has not been established.

DEMAZIN ONCE A DAY should be used with caution in patients with:

- Severe liver impairment, as reduced clearance of loratadine 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 severe renal impairment (creatinine clearance of 30 ml/minute or less), both oral bioavailability and peak plasma concentrations of loratadine and its active metabolite appear to be similar to those individuals with normal renal function.

DEMAZIN ONCE A DAY may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants (e.g. sedatives and tranquilisers). Caution should be used when driving a motor vehicle or operating machinery or

performing potentially dangerous tasks, where loss of concentration may lead to accidents.

INTERACTIONS:

Concomitant use of DEMAZIN ONCE A DAY with inhibitors of cytochrome P-450 enzyme system such as cimetidine, ketoconazole, clarithromycin and erythromycin may increase the plasma concentrations of DEMAZIN ONCE A DAY.

PREGNANCY AND LACTATION:

Safety and efficacy in pregnancy and lactation has not been established. Loratadine and its metabolites

have been detected in breast milk. Small amounts of DEMAZIN ONCE A DAY entering breast milk may cause drowsiness or excitement in infants.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 10 mg once daily (one DEMAZIN ONCE A DAY tablet once daily)

Use of DEMAZIN ONCE A DAY should be limited to 14 days.

Adults with severe liver function impairment: initial dose is 5 mg once daily or 10 mg on alternate days.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Gastrointestinal effects

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

Central and Peripheral Nervous System

Frequent: fatigue, headache, somnolence, blurred vision, confusion, nightmares

Less frequent: sedation, nervousness

Liver

Less frequent: abnormal hepatic function

Skin

Less frequent: rash, alopecia

Other

Less frequent: allergic reactions, anaphylaxis

Special Precautions:

DEMAZIN ONCE A DAY should be discontinued prior to skin tests using allergen extracts as it may inhibit cutaneous histamine response, thus producing false negative results. DEMAZIN ONCE A DAY should be discontinued at least 48 hours before a test.

DEMAZIN ONCE A DAY should be used with caution when the following medical conditions exist and/or in patients using other medication metabolised by the cytochrome P-450 system:

Emphysema; prostatic hypertrophy; narrow angle glaucoma; cardiovascular disorder; epilepsy and 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 headache have been reported. In children, extrapyramidal manifestations and palpitations have been reported.

Treatment of overdose:

Treatment is symptomatic and supportive. After overdose of DEMAZIN ONCE A DAY 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 DEMAZIN ONCE A DAY. Saline cathartics may be of value to dilute bowel contents. DEMAZIN ONCE A DAY is not cleared by haemodialysis.

IDENTIFICATION:

White to off-white, circular, flat with bevelled edged tablet, breakline on one side and plain on other side

PRESENTATION:

Tablets are packed into PVC/ Al blister strips or Al/Al blister strips containing 10 tablets each; packed into

unit carton as 10 (1 blister), 30 (3 blisters) and 250 (25 blisters) tablets

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from excessive moisture and store in a dry place.

Do not remove tablets from unit carton until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

41/5.7.1/0119

NAME AND ADDRESS OF THE APPLICANT

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

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