1.3.1. PACKAGE INSERT

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

CLARITYNE® Plus REPETABS®

COMPOSITION

Active ingredients:

Each CLARITYNE Plus REPETAB contains 5 mg loratadine (micronized) in the tablet coating and 120 mg pseudoephedrine sulphate, equally distributed between the tablet coating and the barrier-coated core. The two active components in the coating are quickly liberated while the release of the decongestant in the core is delayed to ensure a long-lasting effect.

Inactive ingredients: Acacia, calcium sulphate, carnauba wax, *lactose, magnesium stearate, maize starch, microcrystalline cellulose, neutral soap, oleic acid, povidone, rosin, *sucrose, talc, titanium dioxide, white wax and zein.

***Contains sugar:** lactose and sucrose

PHARMACOLOGICAL CLASSIFICATION

A.5.8 Preparations for the common cold, including nasal decongestants and antihistaminics.

PHARMACOLOGICAL ACTION

Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H_1-receptor antagonistic activity.

Pseudoephedrine sulphate is an orally active vasoconstrictor which produces sustained shrinkage of congested upper respiratory mucosa through a sympathomimetic action.

INDICATIONS

CLARITYNE Plus REPETABS are indicated for the relief of nasal and ocular symptoms of upper respiratory mucosal congestion, as in allergic and vasomotor rhinitis.

CONTRAINDICATIONS

CLARITYNE Plus REPETABS are contraindicated in patients who have shown sensitivity or idiosyncrasy to either of its active components, to adrenergic agents or to other drugs of similar chemical structure and in patients receiving monoamine oxidase inhibitors, or within 14 days of stopping such treatment.

Narrow angle glaucoma, urinary retention, severe hypertension or coronary artery disease and hyperthyroidism are relative contra-indications.

The safe use of CLARITYNE Plus REPETABS in children under 12 years of age or in pregnant or lactating mothers has not been established.[SEE PREGNANCY AND LACTATION]

Safety in the elderly has not been established.

WARNINGS and SPECIAL PRECAUTIONS

In patients 60 years of age or older, sympathomimetics are also more likely to cause adverse reactions such as confusion, hallucination, convulsions, central nervous system depression and death. Consequently, caution should be exercised when administering a repeat-action formulation to elderly patients.

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine; an initial dose of one CLARITYNE ~~D~~ Plus REPETAB daily is recommended.

Pseudoephedrine sulphate has been abused. At high doses, subjects commonly experience an elevation of mood, decreased appetite and a sense of increased physical energy, mental capacity and alertness. Anxiety, irritability and loquacity also have been experienced. With continued use, tolerance develops; the user increases the dose and ultimately toxicity occurs. Depression may follow rapid withdrawal.

Effects on Ability to Drive and Use Machinery

Loratadine lacks 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.

MEDICINE/LABORATORY TEST INTERACTIONS

Antihistamines should be discontinued approximately 48 hours prior to skin testing procedures since these medicines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

The *in vitro* addition of pseudoephedrine to sera containing the cardiac isoenzyme MB of serum creatine phosphokinase progressively inhibits the activity of the enzyme. The inhibition becomes complete over 6 hours.

When sympathomimetics are given to patients receiving monoamine oxidase inhibitors, hypertensive reactions including hypertensive crisis may occur.

Increase in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin or cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic). Other medicines known to inhibit hepatic metabolism should be coadministered with caution until definitive interaction studies can be completed.

PREGNANCY AND LACTATION

Safety use of CLARITYNE Plus REPETABS in pregnancy or lactating mothers has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years of age: One CLARITYNE Plus REPETAB twice daily, without chewing the tablet. The duration of treatment should be determined by the duration of symptoms and should not exceed 14 days.

SIDE-EFFECTS

Nervousness, dizziness, fatigue, nausea, abdominal distress, anorexia, thirst, tachycardia, pharyngitis, rhinitis, acne, pruritus, rash, urticaria, arthralgia, confusion, dysphonia, hyperkinesia, hypoesthesia, decreased libido, paresthesia, tremor, vertigo, flushing, postural hypotension, increased sweating, eye disorders, earache, tinnitus, taste abnormality, agitation, apathy, depression, euphoria, paroneiria, increased appetite, change in bowel habits, dyspepsia, eructation, haemorrhoids, tongue discolouration, tongue disorder, vomiting, transient abnormal hepatic function, dehydration, increased weight, hypertension, palpitation, migraine, bronchospasm, coughing, dyspnoea, epistaxis, nasal congestion, sneezing, nasal irritation, dysuria, micturition disorder, nocturia, polyuria, urinary retention, asthenia, back pain, leg cramps, malaise and rigors.

Alopecia, anaphylaxis, abnormal hepatic function, and supraventricular tachyarrhythmias have been reported rarely.

Sympathomimetics should be given with caution in patients with glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy, urinary tract obstruction, cardiovascular disease, increased intraocular pressure or diabetes mellitus and in patients older than 60 years of age.

Sympathomimetics may cause central nervous system stimulation, excitability and convulsions or cardiovascular collapse with accompanying hypotension.

Sympathomimetics reduce the antihypertensive effects of methyldopa, mecamylamine, reserpine and veratrum alkaloids. Increased arrhythmias may occur in conjunction with digitalis. The effect of beta-adrenergic blockers may also be reduced. Antacids increase the rate of pseudoephedrine absorption, while kaolin decreases the absorption rate.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Refer to “Side-Effects”.

Overdosage Information: In the event of overdosage, general symptomatic and supportive treatment should be started immediately and maintained for as long as necessary.

Manifestations: They may vary from central nervous system depression (sedation, apnoea, diminished mental alertness, cyanosis, coma, cardiovascular collapse) to stimulation (insomnia, hallucination, tremors or convulsions) to death. Other signs and symptoms may be euphoria, excitement, tachycardia, palpitations, thirst, perspiration, nausea, dizziness, tinnitus, ataxia, blurred vision and hypertension or hypotension. Stimulation is particularly likely in children, as are atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; hyperthermia and gastrointestinal symptoms).

In large doses sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, pre-cordial pain, palpitations, difficulty in micturition, muscular weakness and tenseness, anxiety, restlessness and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma and respiratory failure.

The Oral LD_{50} values for this combination product were greater than 525 and 1 839 mg/kg in mice and rats, respectively.

Treatment: Treatment is symptomatic and supportive.

Applicant: Bayer (Pty) Ltd

Product name: Clarityne Plus Repetabs

Dosage form and strength: Repetabs 5 mg Loratadine/ 120 mg Pseudoephedrine sulphate

IDENTIFICATION

White to off-white, biconvex, coated tablets.

PRESENTATION

Blister packs of 6 tablets.

STORAGE INSTRUCTIONS

Store at or below 25°C. Protect from moisture.

Keep out of reach of children.

REGISTRATION NUMBER

X/5.8/306

Applicant: Bayer (Pty) Ltd

Product name: Clarityne Plus Repetabs

Dosage form and strength: Repetabs 5 mg Loratadine/ 120 mg Pseudoephedrine sulphate

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd

27 Wrench Road

Isando, 1600

South Africa

1968/011192/07

DATE OF PUBLICATION OF THIS PACKAGE INSERT

Date on the registration certificate: 28 January 1992

Date of the most recently revised package insert: 28 January 1992