Clarinase* Repetabs* Tablets

0HK001531INR

Brand of loratadine and pseudoephedrine sulfate

Schering-Plough

This insert contains basic prescribing information only. For more comprehensive information, a Professional Brochure is available to physicians upon request.

Long-Acting, Non-Sedating Antihistamine/Decongestant Tablets

DESCRIPTION: Each **CLARINASE REPETABS** Tablet contains 5 mg loratadine in the tablet coating and 120 mg pseudoephedrine sulfate equally distributed between the tablet coating and the barrier-coated core. The two active components in the coating are quickly liberated; release of the decongestant in the core is delayed for several hours. Inactive ingredients: acacia, calcium sulfate, carnauba wax, gum rosin, microcrystalline cellulose, oleic acid, medicinal soap, sucrose, talc, titanium dioxide, white wax, zein, lactose anhydrous, corn starch, povidone, magnesium stearate and purified water.

ACTION: Loratadine is a potent long-acting tricyclic antihistamine with selective peripheral H1-receptor antagonistic activity.
Pseudoephedrine sulfate, one of the naturally occurring alkaloids of the Ephedra and an orally administered vasoconstrictor, produces a gradual but sustained decongestant effect facilitating shrinkage of congested mucosa in upper respiratory areas.
The mucuos membrane of the respiratory tract is decongested through the action of the sympathetic nerves.

INDICATIONS AND USAGE: CLARINASE REPETABS Tablets are indicated for the relief of symptoms associated with allergic rhinitis and the common cold including nasal congestion, sneezing, rhinorrhea, pruritus and lacrimation.
CLARINASE REPETABS Tablets are recommended when both the antihistaminic properties of loratadine and the decongestant effect of pseudoephedrine sulfate are desired.

DOSAGE AND ADMINISTRATION: Adults and Children 12 years of age and over: One **CLARINASE REPETABS** Tablet twice a day.

DRUG INTERACTIONS: When administered concomitantly with alcohol, loratadine has no potentiating effects as measured by psychomotor performance studies.
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 drugs known to inhibit hepatic metabolism should be coadministered with caution until definitive interaction studies can be completed.
When sympathomimetics are given to patients receiving monoamine oxidase (MAO) inhibitors, hypertensive reactions, including hypertensive crises may occur. The antihypertensive effects of methyldopa, mecamylamine, reserpine and veratum alkaloids may be reduced by sympathomimetics. Beta-adrenergic blocking agents may also interact with sympathomimetics. Increased ectopic pacemaker activity can occur when pseudoephedrine is used concomitantly with digitalis.
Antacids increase the rate of pseudoephedrine absorption; kaolin decreases it.
Drug/Laboratory Test Interactions: Antihistamines should be discontinued approximately 48 hours prior to skin testing procedures since antihistamines 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 creatinine phosphokinase progressively inhibits the activity of the enzyme. The inhibition becomes complete over six hours.

ADVERSE REACTIONS: During controlled clinical studies with the recommended dosage, the incidence of adverse effects associated with **CLARINASE REPETABS** Tablets was comparable to that of placebo, with the exception of insomnia and dry mouth, both of which were commonly reported. Other reported adverse reactions associated with both **CLARINASE REPETABS** Tablets and placebo included headache and somnolence.
Rare adverse reactions in decreasing order of frequency included nervousness, dizziness, fatigue, nausea, abdominal distress, anorexia, thirst, tachycardia, pharyngitis, rhinitis, acne, pruritus, rash, urticaria, arthralgia, confusion, dysphonia, hyperkinesia, hypoesthesia, decreased libido, paraesthesia, 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, hemorrhoids, tongue discolouration, tongue disorder, vomiting, transient abnormal hepatic function, dehydration, increased weight, hypertension, palpitation, migraine, bronchospasm, coughing, dyspnea, epitaxis, nasal congestion, sneezing, nasal irritation, dysuria, micturition disorder, nocturia, polyuria, urinary retention, asthenia, back pain, leg cramps, malaise and rigors.
During the marketing of loratadine, alopecia, anaphylaxis and abnormal hepatic function have been reported rarely.

CONTRAINDICATIONS: CLARINASE REPETABS Tablets are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components, to adrenergic agents or to other drugs of similar chemical structure. **CLARINASE REPETABS** Tablets also are contraindicated in patients receiving MAO therapy or within fourteen days of discontinuing such treatment and in patients with narrow angle glaucoma, urinary retention, severe hypertension, severe coronary artery disease and hyperthyroidism.

PRECAUTIONS: Sympathomimetics should be used with caution in patients with glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hyperthrophy or bladder neck obstruction, cardiovascular disease, increased intraocular pressure or diabetes mellitus.
Sympathomimetics should be used with caution in patients receiving digitalis.
Sympathomimetics may cause central nervous system (CNS) stimulation, excitability, convulsions, and/or cardiovascular collapse with accompanying hypotension.
In patients 60 years of age or older, sympathomimetics are also more likely to cause adverse reactions such as confusion, hallucination, convulsions, CNS depression and death. Consequently, caution should be excercised when administering a repeat-action formulation to elderly patients.

NEW CODENUMBER **HONG-KONG 0HK001531IN R°**		REPLACES OLD CODE **0HK010301IN**	SUBMISSION **1**
PRODUCTNAME **CLARINASE REPETABS**		OPERATORS **PM9 / KR LS**	DATE OF START UP **20/09/2002**
CONCENTRATION **—**	PRESENTATION **—**	PROFILE **IN04V**	SIZE (MM) **W130 X L265**
COLORS **1** black			
Schering-Plough Heist-op-den-Berg/Belgium		SUPPLIER **PRESSPHARMA/PS/ISDN**	

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 tablet daily is recommended.
Drug Abuse and Dependence: There are no data available to indicate that abuse or dependency occurs with loratadine.
Pseudoephedrine sulfate, like other CNS stimulants, 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.

PEDIATRIC USAGE: Safety and efficacy of **CLARINASE REPETABS** Tablets in children younger than 12 years of age have not yet been established.

USAGE DURING PREGNANCY AND IN NURSING MOTHERS: Safe use of **CLARINASE REPETABS** Tablets during pregnancy has not been established. Therefore, the product should be used only if the potential benefit justifies the potential risk to the fetus.
Since loratadine and pseudoephedrine sulfate are excreted in breast milk, a decision should be made whether to discontinue nursing or discontinue the use of this product.

OVERDOSAGE INFORMATION: In the event of overdosage, general symtomatic and supportive treatment should be started immediately and maintained for as long as necessary.
Manifestations: They may vary from CNS depression (sedation, apnea, 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, precordial 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 1839 mg/kg in mice and rats, respectively.
Treatment: The patient should be induced to vomit, even if emesis has occurred spontaneously. Pharmacologically-induced vomiting by the administration of ipecac syrup is a preferred method. However, vomiting should not be induced in patients with impaired consciousness. The action of ipecac is facilitated by physical activity and by the administration of 240 to 360 millilitres of water. If emesis does not occur within 15 minutes, the dose of ipecac should be repeated. Precautions against aspiration must be taken, especially in children.
Following emesis, ab sorption of any drugs remaining in the stomach may be attempted by the administration of activated charcoal as a slurry with water. If vomiting is unsuccessful, or contraindicated, gastric lavage should be performed. Physiologic saline solution is the lavage solution of choice, particularly in children. In adults, tap water can be used; however, as much as possible of the amount administered should be removed before the next instillation. Saline cathartics draw water into the bowel by osmosis and therefore may be valuable for their action in rapid dilution of bowel content. It is not known whether this product is dialyzable. After emergency treatment, the patient should continue to be medially monitored.
Treatment of the signs and symptoms of overdosage is symptomatic and supportive. Stimulants (analeptic agents) should not be used. Vasopressors may be used to treat hypotension. Short-acting barbiturates, diazepam, or paraldehyde may be administered to control seizures. Hyperpyrexia, especially in children, may require treatment with tepid water sponge baths or hypothermic blanket. Apnea is treated with ventilatory support.

HOW SUPPLIED: CLARINASE REPETABS Tablets are supplied in cartons of 4's, 2 x 7's and 50 x 10's.
STORAGE: Store between 2° and 30°C. Protect from excessive moisture.
Keep out of reach of children.

Further information can be obtained from the doctor or the pharmacist.
Manufactured by Schering-Plough Labo N.V., Heist-op-den-Berg, Belgium under authority of Schering-Plough Corporation.

NEW CODENUMBER HONG-KONG **0HK001531IN V°**		REPLACES OLD CODE **0HK010301IN**	SUBMISSION **1**
PRODUCTNAME **CLARINASE REPETABS**		OPERATORS **PM9 / KR** | **LS**	DATE OF START UP **20/09/2002**
CONCENTRATION **—**	PRESENTATION **—**	PROFILE **IN04V**	SIZE (MM) **W130 X L265**
COLORS **1** black			
Schering-Plough Heist-op-den-Berg/Belgium		SUPPLIER **PRESSPHARMA/PS/ISDN**	