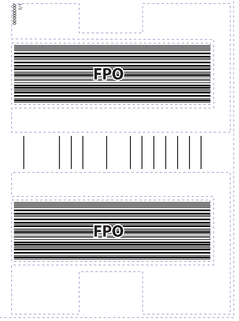

Clarityn-D® 12Hour Repetabs

Brand of loratadine and pseudoephedrine sulfate
Long-Acting, Non-Sedating Antihistamine/Decongestant Tablets

Product Description
Each Claritynn-D® 12Hour Repetabs tablet contains 5 mg loratadine and 120 mg pseudoephedrine sulfate. The two active components in the coating are quickly liberated; release of the decongestant in the core is delayed for several hours.

Also contains: 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.

Claritynn-D® 12Hour Repetabs is available in blister packs.

What is Claritynn-D® 12Hour Repetabs and what is it used for?
Claritynn-D® 12Hour Repetabs relieves symptoms associated with allergic rhinitis and the common cold, including
- blocked nose
- sneezing
- runny, itchy nose
- watery, itchy eyes

Claritynn-D® 12Hour Repetabs contains a combination of two medicines, loratadine (an antihistamine) and pseudoephedrine (a decongestant).
Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances which the body is allergic to. Decongestants clear stuffy or blocked nose.

How to take Claritynn-D® 12Hour Repetabs?
The recommended dose for Claritynn-D® 12Hour Repetabs in adults and children over 12 years is one tablet twice daily.
It does not matter if you take Claritynn-D® 12Hour Repetabs before or after food.

Swallow the tablet whole with a glass of water. Do not crush, break or chew the tablet before swallowing.

If you have severe liver and/or kidney problems, use should generally be avoided.
Be sure to take Claritynn-D® 12Hour Repetabs exactly as your doctor or pharmacist has told you to. If you do not follow their instructions, you may not get relief from your symptoms.

When should Claritynn-D® 12Hour Repetabs not be taken?
Do not take Claritynn-D® 12Hour Repetabs if:
- you are allergic to loratadine, pseudoephedrine or any of its other ingredients
- you are on monoamine oxidase inhibitors, medicines used to treat depression, or within two weeks of discontinuing such treatment
- you have a history of difficulty in swallowing tablets, or have had known upper gastrointestinal narrowing or abnormal esophageal peristalsis
- with narrow angle glaucoma
- with urinary retention
- with severe high blood pressure
- with severe coronary artery disease (heart disease)
- who have hyperthyroidism (overactive thyroid gland)

Do not give this medicine to a child under the age of 12 years.

Pregnancy and breast-feeding
Safe use of Claritynn-D® 12Hour Repetabs during pregnancy has not been established. Therefore, is not recommended for use during pregnancy. Please speak to your doctor or pharmacist if you are pregnant and intend to take Claritynn-D® 12Hour Repetabs.

Since loratadine and pseudoephedrine sulfate are excreted in breast milk, the product is not recommended for use during breast-feeding. Please speak to your doctor or pharmacist if you are breastfeeding and intend to take Claritynn-D® 12Hour Repetabs.

What are the precautionary measures to be observed when taking Claritynn-D® 12Hour Repetabs?
Claritynn-D® 12Hour Repetabs should be used with caution in patients with
- glaucoma or increased intraocular pressure
- stomach ulcer
- intestinal obstruction
- prostate or urinary bladder problems
- heart disease
- diabetes
- 60 years of age or older, because older adults maybe more sensitive to the effects of the medicines
- liver or kidney disease
- hypertension
- hyperthyroidism
- prostatic hypertrophy

Laboratory tests
If you are scheduled to have any skin tests for allergies, you should not take Claritynn-D® 12Hour Repetabs for two days before.

Acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, may occur in isolated cases. If you have signs and symptoms such as fever, redness, or small (generalized) pustules, you should stop taking Claritynn-D® 12Hour Repetabs and consult your doctor.

Possible side effects
Like all medicines, Claritynn-D® 12Hour Repetabs can cause side effects, although not everybody gets them.
Some of the side effects include:
- trouble sleeping
- dry mouth
- headache
- sleepiness

Other rare side effects reported included nervousness, dizziness, fatigue, nausea, abdominal distress, appetite changes, thirst, rapid heart rate, sore throat, runny nose, acne, itch, rash, allergic rash, joint pain, confusion, voice disorders, muscle spasm, reduced sensitivity to touch, decreased libido, prickling sensation on the skin, tremor, sensation of whirling, flushing, blood pressure changes, increased sweating, eye disorders, earache, ringing in the ear, taste abnormality, agitation, lack of interest, depression, intense happiness, feeling paranoid, change in bowel habits, indigestion, belching, hemorrhoids, tongue disorder, vomiting, transient abnormal liver function, dehydration, increased weight, palpitation, migraine, bronchospasm, coughing, shortness of breath, nosebleed, nasal congestion, sneezing, nasal irritation, urination disorders, urinary retention, lack of strength, back pain, leg cramps, malaise, rigors, anorexia.

During the marketing of loratadine, cases of hair loss, severe allergic reaction (including swelling), liver problems, dizziness and convulsion have been reported rarely. Isolated cases of acute generalized exanthematous pustulosis (AGEP), a form of skin reaction, have also been reported with pseudoephedrine-containing products. Pseudoephedrine use has been associated with increased heart rate and increased blood pressure.

If you experience any of these side effects or you notice any not listed in this leaflet, stop taking the medicine and contact your pharmacist or doctor at once.
What other medicine should be avoided whilst taking Claritynn-D® 12Hour Repetabs?
Tell your doctor or pharmacist if you are taking any other medicines, including medicines that are obtained without a prescription. Some medicines should not be taken with Claritynn-D® 12Hour Repetabs. These medicines include:
- Some heart or blood pressure medicines
- monoamine oxidase inhibitors, medicines used to treat depression
- digitalis

These medicines may be affected by Claritynn-D® 12Hour Repetabs, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Signs and symptoms of overdose
Signs and symptoms of overdose may vary from CNS depression (sedation, apnea, diminished mental alertness, cyanosis, coma, cardiovascular collapse) to stimulation (insomnia, hallucination, tremors or convulsions) to death which may be fatal. Other signs and symptoms may be headache, euphoria, excitement, rapid heart rate, palpitations, thirst, perspiration, nausea, dizziness, tinnitus (ringing in the ears), ataxia (lack of muscle coordination), blurred vision and hypertension (high blood pressure) or hypotension (low blood pressure). Stimulation is particularly likely in children, as are atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; hyperthermia (elevated body temperature); and gastrointestinal symptoms).

What should you do in case of an overdose?
In the event of overdose, seek medical help immediately.

How do I store Claritynn-D® 12Hour Repetabs?
Keep the tablets out of reach of children.
Store the tablets at or below 30°C. Protect blister packs from excessive moisture.

For the shelf-life, please refer to labels.

For further information, ask a doctor or pharmacist.

Section Below is meant for Healthcare Professionals

Claritynn-D® 12Hour Repetabs

Brand of loratadine and pseudoephedrine sulfate
Long-Acting, Non-Sedating Antihistamine/Decongestant Tablets

Description
Each Claritynn-D® 12Hour Repetabs tablet contains 5 mg loratadine and 120 mg pseudoephedrine sulfate. 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
Loratadine is a potent long-acting tricyclic antihistamine with selective peripheral H1-receptor antagonistic activity.
Pseudoephedrine
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 mucous membrane of the respiratory tract is decongested through the action of the sympathetic nerves.

Indications and usage
Claritynn-D® 12Hour Repetabs is indicated for the relief of symptoms associated with allergic rhinitis and the common cold including nasal congestion, sneezing, rhinorrhea, pruritus and lacrimation. Claritynn-D® 12Hour Repetabs is 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 Claritynn-D® 12Hour 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 (inhibitors of CYP3A4) or cimetidine (inhibitor of CYP3A4 and CYP2D6) 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, guanethidine, mecamylamine, and reserpine 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.
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 creatine phosphokinase progressively inhibits the activity of the enzyme. The inhibition becomes complete over six hours.

Adverse Reactions
The most frequently reported adverse effects in clinical studies (i.e., >5% incidence) with were insomnia, dry mouth, headache, nervousness and somnolence. The reported incidences of somnolence and headache were comparable to placebo. Palpitations, tachycardia and anorexia, were also reported.
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, paresthesia, tremor, vertigo, flushing, postural hypotension, increased sweating, eye disorders, earache, tinnitus, taste abnormality, agitation, apathy, depression, euphoria, paranoia, 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 (including angioedema), abnormal hepatic function, dizziness and convulsion have been reported rarely. Pseudoephedrine use has been associated with increased heart rate and increased blood pressure.

Isolated cases of acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, have been reported post-market with pseudoephedrine-containing products.

Contraindications
Claritynn-D® 12Hour Repetabs are contraindicated in patients who have shown hypersensitivity or idiosyncrasy to their components, to adrenergic agents or to other drugs of similar chemical structure. Claritynn-D® 12Hour Repetabs are also contraindicated in patients receiving MAO inhibitor therapy or within 2 weeks 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 hypertension, hyperthyroidism, glaucoma, stenosing peptic ulcer, pylorodu odenal obstruction, prostatic hypertrophy 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 exercised when administering a repeat-action formulation to elderly patients.
Acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, may occur with pseudoephedrine-containing products in isolated cases. If signs and symptoms such as fever, erythema or small (generalized) pustules are observed, patients should discontinue the drug and consult their physician.
Because the doses of this combination product cannot be individually titrated, it should generally be avoided in patients with severe hepatic impairment and in patients with severe renal impairment or renal tubular acidosis.
Patients who have a history of difficulty in swallowing tablets, or have had known upper gastrointestinal narrowing or abnormal esophageal peristalsis should not use this product.
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 Claritynn-D® 12Hour Repetabs in children younger than 12 years of age have not yet been established.

Usage during fertility, pregnancy and in nursing mothers
Safe use of Claritynn-D® 12Hour Repetabs during pregnancy has not been established. There was no evidence of animal teratogenicity in reproduction studies performed on rats and rabbits up to 30 times human daily dose. Because animal reproduction studies are not always predictive of human response, it is not recommended for use during pregnancy.
Since loratadine and pseudoephedrine sulfate are excreted in breast milk, the use of the product during breast feeding is not recommended.

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 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 LD50 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, absorption 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 medically 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.

End of Section meant for Healthcare Professionals

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