1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

FLUSIN-C (syrup)

COMPOSITION

Each 5 ml of FLUSIN-C contains 25 mg of pseudoephedrine hydrochloride, 2 mg of chlorphenamine maleate and 50 mg of Vitamin C.

Excipients:

β-carotene, carmellose sodium, glycerol, Nipastat, orange flavour, propylene glycol, purified water, sorbitol solution

Preservative:

Nipastat 0,14 % *m/v*

Contains sugar: Sorbitol solution 3,266 g

Contains sweetener: Sodium cyclamate 7 mg

CATEGORY AND CLASS

A 5.8 Preparations for the common cold including nasal decongestants

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

FLUSIN-C has antihistaminic and decongestant properties.

INDICATIONS

FLUSIN-C is indicated for the symptomatic relief of colds and influenza associated with nasal, sinus and Eustachian tube mucosal congestion.

CONTRAINDICATIONS

FLUSIN-C is contraindicated in:

- Patients with hypersensitivity to any of the ingredients in FLUSIN-C (see COMPOSITION).
- Coronary disease and cardiovascular disease such as ischaemic heart disease, dysrhythmia or tachycardia.
- Pregnancy and lactation (see HUMAN REPRODUCTION).
- Children less than 2 years old.
- Patients sensitive to one antihistamine may be sensitive to others.
- Patients receiving monoamine oxidase inhibitor treatment, or within 14 days of stopping such treatment.

WARNINGS AND SPECIAL PRECAUTIONS

Consult a doctor if no relief is obtained from the recommended dosage.

Do not use this product for more than 7 days without consulting a doctor.

Chlorphenamine maleate

FLUSIN-C may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. Patients should be

advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

Should be used with caution in patients with prostatic hypertrophy, narrow angle glaucoma, emphysema or chronic bronchitis, porphyria. Paradoxical hyperexcitability, nervousness and insomnia may occur in children and in the elderly. Elderly patients are especially susceptible to dizziness, sedation, confusion, hypotension and anticholinergic effects such as dry mouth and urinary retention.

Should be used with care in patients with pyloroduodenal obstruction, epilepsy and severe cardiovascular disorders.

Pseudoephedrine hydrochloride

After 5 to 7 days tachyphylaxis may occur and the product loses effect. If symptoms do not improve, or are accompanied by a fever, consult a doctor. Exceeding the recommended dosage may also result in nervousness, dizziness, sleeplessness, tremulousness or cardiac dysrhythmia. This may also occur in sensitive individuals at small doses. Should be used with caution in patients with hypertension, hyperthyroidism, diabetes mellitus, closed-angle glaucoma, prostatic hypertrophy, phaeochromocytoma, occlusive vascular disease including arteriosclerosis, aneurysms.

Vitamin C (ascorbic acid and sodium ascorbate)

Ascorbic acid should be given with care to patients with hyperoxaluria.

Effects on ability to drive and use machines

Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

Excipients:

FLUSIN-C contains sorbitol and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take FLUSIN-C.

INTERACTIONS

Pseudoephedrine hydrochloride

Reversal of action of antihypertensive medicines may occur and therefore special care is advisable in patients receiving antihypertensive therapy.

Interactions with alpha- and beta-blockers may be complex and can produce hypertensive crisis.

Interactions are possible with tricyclic antidepressants, guanethidine, reserpine, alpha-methyldopa and digoxin.

Should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillation.

An increased risk of dysrhythmias may occur when given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

Aluminium hydroxide mixtures may enhance the absorption of pseudoephedrine.

Chlorphenamine maleate

All sedatives, including alcohol, will potentiate depressant effects on the central nervous system if taken with antihistamines. May enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

Medications tending to cause extrapyramidal reactions and those with anticholinergic effects may be potentiated. These include tricyclic antidepressants, maprotiline and monoamine oxidase inhibitors.

Vitamin C (ascorbic acid and sodium ascorbate)

May interact with desferrioxamine, hormonal contraceptives, fluphenazine and warfarin.

HUMAN REPRODUCTION

The safety of FLUSIN-C in pregnancy and lactation has not been established (see CONTRAINDICATIONS).

DOSAGE AND DIRECTIONS FOR USE

Children 2 to 5 years:

Take 2,5 ml to 5 ml (half to one medicine measure) three times a day.

Children 6 to 12 years:

Take 5 ml to 10 ml (one to two medicine measures) three times a day.

Adults:

Take 10 ml (two medicine measures) four times a day.

SIDE EFFECTS

Pseudoephedrine hydrochloride

Metabolism and nutrition disorders

Appetite may be reduced, altered metabolism, including disturbances of glucose metabolism.

Psychiatric disorders

Fear, anxiety, restlessness, confusion, irritability, psychotic states and insomnia.

Nervous system disorders

Tremor, headache is also common.

Cardiac disorders

Vasoconstriction with resultant hypertension. The rise in blood pressure may produce cerebral haemorrhage and pulmonary oedema. There may also be reflex bradycardia, but stimulation of β_1-adrenergic receptors of the heart may produce tachycardia and cardiac dysrhythmias, anginal pain, palpitations and cardiac arrest. Hypotension with dizziness and fainting and flushing may occur. Anginal pains may be precipitated in patients with angina pectoris.

Respiratory, thoracic and mediastinal disorders

Dyspnoea.

Gastrointestinal disorders

Nausea and vomiting may occur. Hypersalivation.

Renal and urinary disorders

Difficulty in micturition and urinary retention.

General disorders and administrative site conditions

Weakness, sweating.

Chlorphenamine maleate

Blood and the lymphatic system disorders

Agranulocytosis, leucopenia, haemolytic anaemia and thrombocytopenia have been reported.

Immune system disorders

Hypersensitivity reactions (including bronchospasm, angioedema and anaphylaxis).

Psychiatric disorders

Confusion, hallucinations, sleep disturbances, depression.

Nervous system disorders

Sedation, drowsiness, convulsions, headache, dizziness, incoordination, fatigue, nervousness, insomnia, paresthesias, tingling and tremors. Extrapyramidal effects with muscle spasms and dystonia. Anticholinergic effects with ataxia.

Eye disorders

Anticholinergic effects with blurred vision.

Ear and labyrinth disorders

Tinnitus.

Cardiac disorders

Palpitation and dysrhythmias, hypertension, hypotension, tachycardia.

Vascular disorders

Anticholinergic effects with flushing.

Respiratory, thoracic and mediastinal disorders

Dryness of the mouth, throat and respiratory passages, thickening of mucous, tightness of the chest.

Gastrointestinal disorders

Gastrointestinal disturbances such as nausea, vomiting, epigastric pain and diarrhoea have occurred. Reduction in tone and motility of the gastrointestinal tract, resulting in constipation and gastric reflux.

Skin and subcutaneous tissue disorders

Photosensitivity and skin rash, allergic dermatitis, may cause rashes. Hair loss.

Musculoskeletal, connective tissue and bone disorders

Myalgia, heaviness and weakness of the hands.

Renal and urinary disorders

Urinary retention or frequency, dysuria.

General disorders and administrative site conditions

Lassitude, drug fever, sweating.

Vitamin C (ascorbic acid and sodium ascorbate)

Blood and the lymphatic system disorders

Large doses of vitamin C (ascorbic acid and sodium ascorbate) have resulted in haemolysis in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Gastrointestinal disorders

Large doses are reported to cause diarrhoea and other gastrointestinal disturbances.

Renal and urinary disorders

Large doses are associated with the formation of renal calcium oxalate calculi.

General disorders and administrative site conditions

Tolerance may be produced with prolonged use of large doses.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Chlorphenamine Maleate

Symptoms

Central excitatory effects constitute the greatest danger in overdose. Symptoms include drowsiness or paradoxical excitement, hallucinations, ataxia, incoordination, athetosis and convulsions. Fixed dilated pupils with a flushed face, sinus tachycardia, dyspnoea, urinary retention, dry mouth and fever. Terminally deepening coma and cardiorespiratory collapse. Children and the elderly are more likely to exhibit anticholinergic and central nervous system stimulant effects. The elderly are prone to hypotension.

Treatment

The stomach should be emptied by emesis or lavage. There is no specific antidote and treatment is symptomatic and supportive. It may be necessary to treat extrapyramidal reactions with barbiturates or diphenhydramine. The patient must be taken to a doctor or hospital immediately as specialised treatment may be necessary.

Pseudoephedrine Hydrochloride

Symptoms

Pseudoephedrine overdosage produces central nervous system stimulation with excitement, restlessness, rapid speech, hallucinations, hypertonicity and hyperreflexia with dilated pupils and tachycardia.

Treatment

Beta-blockers may be administered for tachycardia. Potassium supplements may be required.

IDENTIFICATION

A light orange, viscous, slightly opaque syrup with a distinct smell of oranges.

PRESENTATION

100 ml is packed into a round amber glass bottle and sealed with a white polypropylene cap with an expanded polyethylene liner.

STORAGE INSTRUCTIONS

Store in a cool place at or below 30 °C.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

27/5.8/0523

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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