SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gripgo Hotmix (Lemon Flavour) Granules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet (5g) contains:
Paracetamol BP……..…….. 750.0 mg
Ascorbic Acid coated eq. to Ascorbic Acid BP…60.0 mg
Phenylephrine HCl BP……..10.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Light yellow to yellow coloured granular powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gripgo Hotmix Granules are indicated for short-term relief from symptoms of cold and flu, including headache, fever, nasal congestion, sinusitis and pain associated with it, sore throat, body ache and acute nasal catarrh.

4.2 Posology and method of administration

Posology

Adults and children above 12 years:
Take one sachet every 6-8 hours if necessary. Do not take sooner than in 6 hours. Do not take more than 4 sachets a day. Maximum duration of treatment without doctor's prescription is 7 days.

Dosage and usage advice. The medicine is to be taken orally. Empty the contents of one sachet into a glass and half fill it with hot water and then stir well. Add cold water if necessary.

Children. The medicine is not recommended in children under 12 years.

Route of administration: Oral

4.3 Contraindications

Hypersensitivity to components of the drug, sever liver and/or renal impairment, congenital hyperbilirubinaemia, Glucose-6-phosphate dehydrogenase deficiency, rare hereditary fructose intolerance, glucose-galactose malabsorption or sucrose isomaltose deficiency, alcoholism, blood diseases, frank anemia, leucopenia, thrombosis, thrombophlebitis; in state of overexcitement: in state of sleep disturbance: severe arterial hypertension; organic diseases of cardiovascular system (including atherosclerosis); glaucoma, decompensated heart failure, cardiac conduction disorder, severe atherosclerosis, predisposition to angiospasms, ischemic heart disease, acute pancreatitis, prostatic hypertrophy, severe diabetes, epilepsy, hyperthyreosis, at elderly age, angle- closure glaucoma, children under 12 years, pregnancy, lactation. Do not use the medicine along with monoamine

oxidase inhibitors (MOI) and for 2 weeks after discontinuation of MOI inhibitors, it is contraindicated to patients taking tricyclic antidepressants or beta-blockers.

4.4 Special warnings and precautions for use

Avoid concomitant use with other drugs prescribed for symptomatic treatment of cold and flu, vasoconstrictor agents for treatment of rhinitis, drugs containing paracetamol. Patients with renal and hepatic impairment, diabetes, cardiovascular diseases, hyperthyroidism, phaeochromocytoma, Raynaud's disease, benign hyperbilirubinemia are commended to consult the doctor as for possibility of use of the medicine. During long treatment it is recommended to monitor liver function and pattern in peripheral blood. Use of phenylephrine which comprises the medicine, may cause angina attacks. 1 sachet (1 dose) contains 2.9 g sugar. This must be considered by patients with diabetes. Do not exceed the stated dose. If the patient’s condition does not improve during the treatment with the medicine, consult the doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Metoclopramide and domperidone can increase the rate of absorption of paracetamol, whereas cholestyramine can decrease it. Long-term regular daily administration of paracetamol can increase anticoagulant effect of warfarin and the risk of hemorrhage. Barbiturates decrease antipyretic effect of paracetamol. Anti-convulsants (including phenytoin, barbiturates, carbamazepine), which stimulate activity of hepatic microsomal enzymes, can increase toxic effect of paracetamol on the liver due to increased level of drug transformation into hepatotoxic metabolites. Concordant administration of high doses of paracetamol with isoniazid increases the risk of development of hepatotoxic syndrome. Paracetamol reduces efficacy of diuretics. Do not use simultaneously with alcohol. Interaction of phenylephrine with monoamine oxidase inhibitors has hypertensive effect, with tricyclic antidepressants - increased risk of cardiovascular disorders, with digoxin and cardiac glycosides - palpitation disorder or myocardial infarction. Phenylephrine with other sympathomimetics increases risk of development of cardiovascular system side effects. Phenylephrine can reduce efficacy of beta-blockers and other anti-hypertensive drugs (reserpine, methyldopa, etc.) along with the increased risk of hypertension and other cardiovascular system disorders. Ascorbic acid taken orally increases absorption of penicillin, iron, decreases efficacy of heparin and indirect anticoagulants, increases the risk of crystalluria in treatment with salicylates. Antidepressants, anti-Parkinson and antipsychotic drugs, phenothiazine derivatives increase the risk of urine retention, dry mouth, constipation. Glucocorticosteroids lead to the increased risk of glaucoma development. Absorption of vitamin C is decreased when oral contraceptives are taken simultaneously with fruit or vegetables juices, alkaline drinks. Concordant administration of Vitamin C and deferoxamine increases tissue toxicity of iron especially in the heart muscle, which may lead to circulatory decompensation. Vitamin C can be taken only in 2 hours after the injected dose of deferoxamine. Long-term administration of high doses in patients undergoing the treatment with disulfiram inhibits the reaction of disulfiram with alcohol. High doses of the medicine reduce the efficacy of tricyclic depressants.

4.6 Fertility, pregnancy and lactation

Do not take this medicine during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

If during the treatment with the medicine the patient experiences dizziness, it is not recommended to drive or operate other machines.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders:

rash, pruritis, urticaria, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.
Immune system disorders: in individual cases - anaphylactic shock, angioedema.

Neurological disorders:
headache, dizziness, psychomotor agitation, disorientation, preoccupation, nervous exaltation, apprehension, annoyance, sleep disturbance, confused mental state, depressed states, tremor, prickling and heavy sensation in limbs, tinnitus.

Eye disorders:
vision and accommodation disorders, increased intraocular pressure y

Gastrointestinal tract disorders:
nausea, vomiting, dry mouth, epigastric discomfort and pain, hypersalivation, loss of appetite, enhanced activity of liver enzymes, hepatonecrosis (in high doses), hearthburn, diarrhea.

Hemopoietic system disorders:
anemia, sulfhemoglobinemia and methemoglobinemia, hemolytic anemia.

Urinary system disorders:
urination disorder, crystalluria, formation of urate and oxalate stones in kidneys and excretory tracts.

Cardiovascular system disorders:
arterial hypertension, tachycardia or reflex bradycardia, dyspnoea, cardialgia, arrhythmia.

Respiratory system disorders:
bronchospasm in patients susceptible to aspirin and other non-steroid anti-inflammatory drugs.

Others:
general weakness, excessive sweating, hypoglycemia, hyperglycemia, glucosuria, disorders in zinc and copper metabolism.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Paracetamol:
Symptoms:
Overdose as a rule is inflicted by paracetamol and its manifestations are pale skin, anorexia, nausea, vomiting, abdominal pain, hepatonecrosis, elevated liver transaminases, increased prothrombin ratio. Symptoms of liver damage are observed in 12-48 hours after overdose. Disorders of glucose metabolism and metabolic acidosis may occur. In case of severe poisoning hepatic impairment may progress and inflict development of toxic encephalopathy with impairment of consciousness, and in individual cases with lethal outcome. Acute kidney injury with severe tubular necrosis may develop even without severe kidney damage. Cardiac arrhythmia was also observed. Liver damage is possible in adults who took 10 g and more of paracetamol, and in children who took more than
150 mg/kg of paracetamol. Long-term treatment in high doses may lead to aplastic anemia, pancytopenia, agranulocytosis, neutropenia, leukopenia, thrombocytopenia. High doses may cause urinary system disorders - nephrotoxicity, renal colic, interstitial nephritis, papillary necrosis).

Treatment:

In case of overdose of paracetamol first medical aid is required even in absence of overdose symptoms. Conduct gastric lavage with further administration of activated carbon and symptomatic treatment. Administration of paracetamol antidotes - N- acetylcysteine intravenously and methionine orally - may have a favourable effect for 48 hours after the overdose.

Phenylephrine
Symptoms:
Overdose caused by the action of phenylephrine may lead to excessive sweating, psychomotor agitation or central nervous system depression, headache, dizziness, somnolence, impairment of consciousness, heart rhythm disorder, tachycardia, premature ventricular contraction, tremor, hyperreflexia, spasms, nausea, vomiting, irritability, anxiety, increase in arterial blood pressure.

Treatment:
In case of overdose it is recommended to conduct symptomatic therapy, administration of alpha-blockers such as phentolamine in case of severe hypertension.

Ascorbic acid
Symptoms:
Overdose caused by ascorbic acid may have the following manifestations: nausea, vomiting, abdominal bloating and pain, pruritis, skin rash, overexcitement. High doses of ascorbic acid (more than 3000 mg) may cause temporary osmotic diarrhea and gastrointestinal distress.

Treatment:
Gastric lavage, alkaline drink, activated carbon or other absorbents.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Paracetamol, combinations excl. psycholeptics, ATC code: N02BE51

Mechanism of action
Paracetamol is an analgesic and antipyretic drug. It acts as an inhibitor of synthesis of prostaglandins in the central nervous system, it acts on heat regulating center in the hypothalamus. Phenylephrine hydrochloride is a sympathomimetic. Its primary action is direct stimulation of adrenergic receptors, mainly alpha- adrenergic receptors and partially - with indirect effect caused due to release of noradrenaline. Phenylephrine hydrochloride reduces swelling of the nasal mucous. It works by narrowing of arteriols, increases general peripheral vascular resistance and arterial pressure. Ascorbic acid is added into the drug composition to replenish the loss of Vitamin C, which may occur at the beginning of a viral infection. Ascorbic acid is known to play an important role in the protection of the organism against infections, it is also necessary for T-lymphocytes to function normally and for efficient phagocytic activity of leukocytes. No active substance causes drowsiness.

The authority/EFDA will review new information on this medicinal product at least every year and this SmPC will be updated as necessary.

5.2 Pharmacokinetic properties

Paracetamol
Is readily absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine, mainly as glucuronide and sulphate conjugates.

Phenylephrine Hydrochloride

Due to irregular absorption and first pass metabolism by monoamine oxidase in the gut and liver, phenylephrine has reduced bioavailability from the gastrointestinal tract. It is excreted in the urine almost entirely as the sulphate conjugate.

For ascorbic acid.
Absorption.
Ascorbic acid is absorbed mainly in the upper part of the small intestine through sodium-dependent active transport. If ascorbic acid is present at high concentrations, then its absorption also occurs via passive diffusion. With the increasing of ascorbic acid oral doses from 1 g to 12 g, the drug absorption specific weight was decreased (approximately 50% to 15%). The gastrointestinal tract disorders (gastritis, ulcer, constipation, diarrhea, helminthosis, giardiasis), the intake of fresh fruit and vegetable juice and alkaline drinking may disturb the absorption of vitamin C. Distribution: The binding of ascorbic acid to blood plasma proteins is approximately 24%. As a rule, the ascorbic acid blood serum concentration is 10 mg/L (60 μmoll/L) in terms of adequate ascorbic acid intake. The reduction of ascorbic acid blood serum concentration below 4 mg/l (20 μmoll/L) indicates poor intake of vitamin C. Metabolism: Ascorbic acid is metabolised partly via dehydroascorbic acid to oxalic acid and other products. When ingested inexcessive quantities, ascorbic acid is largely excreted in unchanged form in the urine and faeces. Ascorbic-acid-2-sulphate also appears as ascorbic acid metabolite in the urine. Smoking and ethyl alcohol abuse accelerates ascorbic acid decay (transformation into inactive metabolites), sharply decreasing its reserve in organism. The physiological level of ascorbic acid depot in organism is about 1.5 g. It deposes in the back of the pituitary, adrenal cortex, epithelium of the eye, intermediate cells of seminal glands, ovaries, liver, brain, spleen, pancreas, lungs, kidneys, intestine wall, heart, muscle, thyroid gland. It easily penetrates from plasma into leucocytes, platelets, and almost all tissues.

Elimination:
Unchanged ascorbate and its metabolites are excreted by the kidneys, intestine, through sweat and penetrate into breast milk. The half-life of ascorbic acid depends on the route of administration, the quantity administered and the rate of absorption. Following an ascorbic acid oral dose of 1 g the half-life is about 13 hours. When up to 3 g ascorbic acid/day is taken, the main route of excretion is renal. With doses exceeding 3 g/day, it is excreted both in the faeces and urine (unchanged).

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose, Sodium saccharin, Lemon flavor, Quinoline Yellow WS, Povidone K-30, Isopropyl alcohol, Purified water, Citric acid, Sodium Citrate, Starch LM 1500.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in a dry place protected from light at temperature below 30°C. Keep out of reach of children.

6.5 Nature and contents of container

Granular powder for preparation of oral solution packed in sachets.
Each sachet contains 5 g granules. Such 10 sachets are enclosed in a carton pack along with pack insert.

6.6 Special precautions for disposal <and other handling>

No special requirements for disposal.

7. MARKETING AUTHORISATION HOLDER

Kusum Healthcare Pvt. Ltd.
SP-289(A), RIICO Industrial Area,
Chopanki, Bhiwadi, Dist. Alwar, Rajasthan, India

8. MARKETING AUTHORISATION NUMBER(S)

05888/07621/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 April 2021

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines