SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Gripgo Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablets contains:
Paracetamol BP……500 mg
Caffeine Anhydrous USP…….30 mg
Phenylephrine hydrochloride USP……...10 mg
Chlorpheniramine maleate USP…….2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.
White, capsule shaped biconvex tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Gripgo is indicated for the treatment of symptoms of influenza and other acute respiratory viral diseases, accompanied by fever, headache and muscle pain, runny nose, allergic component in the form of nasal congestion, sneezing, lacrimation.

4.2 Posology and method of administration

Posology

Adults and children above 12 years of age are prescribed 1 tablet 3 to 4 times a day with water. The maximum daily dose is 4 tablets. The duration of the course of treatment is not more than 3 - 5 days. Do not exceed these doses.

4.3 Contraindications

- hypersensitivity to the components of the drug
- simultaneous administration of tricyclic antidepressants, MAO inhibitors, beta-blockers
- simultaneous use of drugs containing paracetamol
- arterial hypertension
- hyperthyroidism
- hypertrophy of the prostate
- chronic alcoholism
- kidney and liver diseases
- pregnancy and lactation period
- children under 12 years old

4.4 Special warnings and precautions for use

Use with caution in patient with tendency of bradycardia, heart failure, coronary heart disease, atherosclerosis, hypertension, prostatic hypertrophy, elderly people.
Patients with pathology of the blood system need control of blood tests. During the treatment with Gripgo, the use of alcoholic beverages is strictly prohibited.

This medicine contains less than 1 mmol sodium (23 mg) per tablet; that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Do not prescribe Gripgo with other drugs containing paracetamol, as well as other non-steroidal anti-inflammatory drugs.
The risk of developing a hepatotoxic effect increases with the simultaneous use of barbiturates, diphenin, carbamazepine, rifampicin, zidovudine and other inducers of microsomal liver enzymes. Barbiturates reduce the antipyretic effect of paracetamol.
Do not simultaneously use the drug with tricyclic antidepressants, MAO inhibitors and within 14 days after their withdrawal because of the possibility of enhancing the hepatotoxic effect of paracetamol. Against the background rezinpina possible increase in blood pressure. Ergot alkaloids increases arrhythmogenicity.
With simultaneous administration of metoclopramide, domperidone or cholestyramine, the absorption of paracetamol decreases.
Fluconazole, ketoconazole, mexiletine and terbinafine can moderately increase the concentration of caffeine in the plasma, possibly amplifying its effect and toxicity.
The drug enhances the effect of indirect anticoagulants.

4.6 Fertility, pregnancy and lactation

Gripgo is a combination drug with phenylephrine having vasoconstrictive action which can compromise fetal circulation and milk production. It is secreted in milk. Hence Gripgo is not advised to be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

When taking Gripgo, you should be careful when driving vehicles and working with potentially dangerous machines, which is due to the possibility of reducing the reaction rate.

4.8 Undesirable effects

- skin rash, itching, hives, angioedema
- dizziness, falling asleep, increased excitability
- increased blood pressure, tachycardia
- nausea, vomiting, epigastric pain, dry mouth
- retention of urine
- paresis of accommodation, increased intraocular pressure, mydriasis
- anemia, thrombocytopenia, agranulocytosis, hemolytic anemia, aplastic anemia, methemoglobinemia, pancytopenia
- hepatotoxic action
- nephrotoxicity (papillary necrosis)
- bronchial obstruction.
- with prolonged use, especially in high doses, the development of methemoglobinemia, anemia, nephrotoxic and hepatotoxic effects is possible.

With caution - pronounced arteriosclerosis of the coronary arteries, arterial hypertension, thyrotoxicosis, pheochromocytoma, diabetes mellitus, bronchial asthma, chronic obstructive pulmonary disease, deficiency of glucose-6-phosphate dehydrogenase, blood diseases, congenital hyperbilirubinemia (Gilbert syndrome, Dubin-Johnson and Rotor syndrome), hepatic and / or renal failure, angle-closure glaucoma, prostatic hyperplasia.

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

Symptoms:
Nausea, vomiting, dry mouth, nose and throat, pain in the stomach or liver, sweating, breathing disorder, confusion, bradycardia, arterial hypertension, tachycardia, arrhythmia, facial flushing. In severe cases, hepatic failure and coma develops. Treatment: Gastric lavage and use of sorbents, if necessary, symptomatic therapy. The antidote of paracetamol is acetylcysteine, methionine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics. Anilides. Paracetamol in combination with other drugs excluding psycholeptics, ATC code: N02BE51

Gripgo is a combined medicinal product, the effect of which is due to the components that make up its composition.

Paracetamol is an analgetic-antipyretic with antipyretic and analgesic properties, as well as a slight anti-inflammatory effect associated with the effect of paracetamol on the hypothalamic center of thermoregulation and its ability to inhibit the synthesis of prostaglandins.
Caffeine is an alkaloid of the methylxanthine group, which directly stimulates the respiratory and vasomotor centers of the brain, improves the physical and emotional state of the patient, thereby reducing the manifestations of asthenia in infectious diseases. Increases the analgesic effect of paracetamol.

Phenylephrine hydrochloride is an adrenomimetic agent that reduces edema and hyperemia in the upper respiratory tract and sinuses, which helps improve nasal breathing. It stimulates mainly alpha-adrenergic receptors, due to which there is a narrowing of peripheral vessels and a decrease in their permeability, the formation of mucous secretion decreases.
Chlorpheniramine maleate is an antihistamine that reduces the allergic component of an infectious disease. Competitively blocks histamine H1-receptors and prevents the development of histamine effects, eliminates the common cold, itching in the nose and pain in the eyes.

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 rapidly and almost completely absorbed from the gastrointestinal tract. The maximum concentration in the blood plasma is achieved 2 hours after oral administration. Approximately 25% of paracetamol binds to blood plasma proteins. Paracetamol is metabolized in the liver and is excreted mainly with urine in the form of glucuronide and sulfate conjugates. Less than 5% is excreted in unchanged form. The half-life is 1 to 4 hours. Caffeine is rapidly absorbed and distributed to all organs and tissues of the body, including the central nervous system, embryonic tissues and breast milk. It is rapidly metabolized and excreted mainly in the urine (70%).
Phenylephrine is rapidly absorbed after oral administration, peak plasma concentrations are reached after 1 to 2 hours, a suction level of 70%, a half-life of 2 to 3 hours, is excreted predominantly in the urine.
Chlorpheniramine maleate is rapidly absorbed from the gastrointestinal tract and distributed to all tissues of the body. Approximately 25% is binds with plasma proteins.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30°C.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

10 tablets are packed in a PVC/PVDC blister. 1 or 10 such blisters of 10 tablets (1x10 & 10x10) are packed in a carton along with packaging insert.

1 blister of 10 tablets is packed in a monocarton. 10 such monocartons are packed in 1 outer carton (10x1x10).

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)

05123/07187/NMR/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 April 2020

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