SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

FLUCOLDEX-E SUSPENSION
(Paracetamol, Chlorphenamine Maleate & Phenylephrine HCl Oral Suspension)

Strength
Composition:

Each 5 ml (one teaspoonful) Contains:
Paracetamol BP 125 mg
Chlorphenamine Maleate BP 2 mg
Phenylephrine HCl BP 1 mg
Colour: Carmoisine
Flavoured Syrupy base QS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml (one teaspoonful) Contains:
Paracetamol BP 125 mg
Chlorphenamine Maleate BP 2 mg
Phenylephrine HCl BP 1 mg
Colour: Carmoisine
Flavoured Syrupy base QS
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Suspension

Pink colored homogenous suspension having strawberry flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of Cold and Influenza, for relieve of Fever and pains, connected with Influenza and Simple colds.
At the first symptoms of cold take FLUCOLDEX-E Suspension as per indication of dosage. For Maximum relief, take a full course of treatment with FLUCOLDEX-E suspension. It is also indicated for sinusitis, nasal congestion, runny nose, sneezing. It may not cause Cough Congestion as well as Dental Caries.

4.2 Posology and method of administration

Posology

Posology: From 1 to 4 Years:-1 teaspoonful every 6 hours
5 to 8 years:-2 teaspoonful every 6 hours.

9 to 12 years:- 2 to 4 teaspoonful every 6 hours.
OR As directed by the Physician.
Liquid for oral administration.
DO NOT EXCEED THE GIVEN DOSAGE.
Before taking Flucoldex-E, please consult doctor in case you are taking any other medicines.

Method of administration: Oral

4.3 Contraindications

Hypersensitivity of any of the ingredients

4.4 Special warnings and precautions for use

Do not exceed recommended dosage. In case of accidental overdosage, contact a Physician immediately. Overdose of Paracetamol may be injurious to liver.

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6 Fertility, pregnancy, and lactation

There is no information available regarding this for this combination. Physician's advice has to be followed. Individual labels of the active ingredients have to be checked for more information.
Paracetamol
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk, but not in a clinically significant amount. Available published data do not contraindicate breast feeding.
Phenylephrine hydrochloride
The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. In addition, because phenylephrine may reduce placental perfusion, the product should not be used in patients with a history of pre-eclampsia.
In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding.

4.7 Effects on ability to drive and use machines

Patients who experience drowsiness should refrain from driving, engaging in potentially hazardous activities or operation machinery.

4.8 Undesirable effects

• Nervousness

• Dizziness, or sleeplessness

Paracetamol

• Adverse effects of paracetamol are rare, but hypersensitivity including skin rash may occur.

There have been a few reports of blood dyscrasias including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

• Acute pancreatitis after ingestion of above normal amounts.

Phenylephrine hydrochloride

• High blood pressure with headache and vomiting, probably only in overdose.

Rarely palpitations. Also, rare reports of allergic reactions and occasionally urinary retention in males.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important as it allows continued monitoring of the benefit–risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions to the marketing authorisation holder or, where applicable, via the national reporting system.

4.9 Overdose

Symptoms of overdose may include: nausea, vomiting, drowsiness, blurred vision, slowed breathing, seizures. In the event of overdose stop the treatment and consult your doctor.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorpheniramine antagonises competitively the effects of histamine on H1-receptors and also has weak antimuscarinic and moderate antiserotonin and local anaesthetic actions. It penetrates the brain and causes stimulation or sedation in animals.

Phenylephrine is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha adrenergic activity and is without stimulating effects on the central nervous system. The sympathomimetic effect of Phenylephrine produces vasoconstriction which in turn relieves nasal congestion.

Paracetamol: Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis within the central nervous system.

5.2 Pharmacokinetic properties

Chlorpheniramine maleate is almost completely absorbed after administration by mouth, peak plasma concentrations occurring at about 2.5 to 6 hours. The drug is widely distributed including passage into the CNS, with a volume of distribution of between 1 and 10L/KG. About 70% of chlorpheniramine in the circulation is protein bound. Chlorpheniramine undergoes some first pass metabolism and enterohepatic recycling. Chlorpheniramine is extensively metabolised, principally to inactive desmethylated metabolites which are excreted primarily in the urine, together with about 35% unchanged drug. Only trace amounts are excreted in the faeces. The mean elimination half life has been reported to be about 30 hours, with mean values ranging from 2 to 43 hours.

Phenylephrine is readily absorbed after oral administration but is subject to extensive presystemic metabolism, much of which occurs in the enterocytes. As a consequence, systemic bioavailability is only about 40%. Following oral administration, peak plasma concentrations are achieved in 1-2 hours. The mean plasma half life is in the range 2-3 hours. Penetration into the brain appears to be minimal.

Following absorption, the drug is extensively metabolised in the liver. Both phenylephrine and its metabolites are excreted in the urine.

The volume of distribution is between 200 and 500 litres, but there are no data on the extent of plasma protein binding.

Paracetamol: Paracetamol is absorbed rapidly and completely mainly from the small intestine producing peak plasma levels after 15-20 minutes following oral dosing.

In a study of healthy controls fasted overnight the Tmax for an equivalent product compared to two tablets of standard paracetamol was 20 minutes versus 35 minutes (p=0.0865). However, the speed to achieve 10 µg/ml for the product was faster than a standard paracetamol (17 minutes versus 30 minutes).

The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a T1/2 of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (>80%) which are excreted in urine.

5.3 Preclinical safety data

The antihistaminic potency of chlorpheniramine is confined mainly to

its (+)-isomer. The racemate is similarly or slightly more toxic because of the contribution of (-)- isomer. The toxicity may therefore be non-specific, perhaps attributable to local anaesthetic action and the toxic effects (excitation/sedation, coma, convulsions and death) resemble those of other classic H1 antihistamines. Toxic doses may cause hypotension attributable to myocardial depression, an effect which is clearer with the (-)-isomer.

The experimental data on the carcinogenicity and mutagenicity of Chlorpheniramine indicate lack of these adverse effects, but the racemate and the (+)-isomer have shown some embryotoxicity in fertility tests.
Effective antihistaminic concentrations of chlorpheniramine in vitro are about 1-10µg/L and oral doses of 0.2-1 mg/kg antagonise histamine- induced bronchospasm in guinea pigs. There is no separate data for the other components.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Paraben BP, Sodium Propyl Paraben BP, Sodium Benzoate BP, Sodium Saccharin BP, Citric Acid BP (Monohydrate), Xanthan Gum BP (Plain), Guar BP (Delca P- 225), Arrowcell CRT / Arrow Gum Super, Sucrose BP, Enisweet EP Powder, Colour Carmosine, Strawberry NTL-8778 Flavour, Purified Water BP.

6.2 Incompatibilities

None

6.3 Shelf life

36 months from the date of manufacturing.

6.4 Special precautions for storage

Store below 30°C, at a dry place.
Protect from light.
Keep medicine out of reach of children.

6.5 Nature and contents of the container

100 ml Amber coloured round PET bottle with 25 mm Golden Plain PP Caps packed in a carton with a leaflet and measuring cup. 10 such cartons are wrapped with PVC Shrink and are packed in 7-Ply Corrugated Box and sealed with Transparent BOPP Tape.

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORIZATION HOLDER

GALAXY PHARMACEUTICAL LIMITED,

P.O. Box 39107-00623,
Nairobi, Kenya.

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8. MARKETING AUTHORIZATION NUMBER

H2006/432

9. DATE OF FIRST REGISTRATION

2nd August 2006

10. DATE OF REVISION OF THE TEXT

2nd March 2026