1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINE FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME (AND DOSAGE FORM)

CO-FLEM (syrup)

COMPOSITION

Each 5 ml syrup contains:

Carbocisteine	250 mg

Excipients:

Colour sunset yellow (CI no. 15985), flavour tangerine liquid W/S LR 78772, methyl parahydroxybenzoate, sodium hydroxide (pellets), sucrose

Preservative:

Methyl parahydroxybenzoate	0,1 % *m/v*

CONTAINS SUGAR: SUCROSE

PHARMACOLOGICAL CLASSIFICATION

A 10.2.2 Medicines acting on the respiratory system. Other

PHARMACOLOGICAL ACTION

Carbocisteine reduces the viscosity of non-infected secretions from mucous cells in the respiratory tract.

INDICATIONS

Adjunctive therapy in respiratory tract disorders characterised by excessive viscous mucous in the absence of infection.

CONTRAINDICATIONS

Active peptic ulcer. Hypersensitivity to any of the ingredients.

DOSAGE AND DIRECTIONS FOR USE

Adults: Two to three medicine measurefuls (10 ml to 15 ml) three times daily.

Children:

5 to 12 years: One medicine measureful (5 ml) three times daily.

2 to 5 years: Half a medicine measureful (2,5 ml) given twice to four times daily (according to age).

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Nausea, diarrhoea and headache may occur. Gastro-intestinal bleeding, skin rash, palpitations, dizziness and heartburn have been reported.

CO-FLEM should be administered with caution to patients with a history of gastric or duodenal ulcer.

The safety of CO-FLEM in pregnancy has not been established.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Nausea and vomiting. Treatment is symptomatic and supportive.

IDENTIFICATION

Clear orange syrup.

PRESENTATION

200 ml amber glass bottles and plastic bottles containing 200 ml, 500 ml and 2,5 litre.

Not all packs and pack sizes are necessarily marketed

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

V/10.2.2/291

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

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