SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM : EXPIGEN® COUGH SYRUP

COMPOSITION:

Each 10 ml contains:

Sorbimacrogol laurate 300	36,33 mg
Ammonium chloride	34,00 mg
Preservative: Sodium benzoate	0,12 % *m/v*
Contains sugar: Sucrose	6,00 g

ALCOHOL FREE

List of excipients: Aniseed oil, caramel, citric acid, glycerin, sodium benzoate, sucrose and purified water.

PHARMACOLOGICAL CLASSIFICATION:

A: 10.1 Antitussives and expectorants

INDICATIONS:

For the alleviation of cough.

CONTRAINDICATIONS:

EXPIGEN COUGH syrup is contraindicated in the presence of impaired hepatic or renal function.

WARNINGS AND SPECIAL PRECAUTION:

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take EXPIGEN COUGH.

Effects on ability to drive and use machines

Persons operating machinery or driving cars should exercise caution after taking the medicine.

INTERACTIONS

Sorbimacrogol laurate 300 may increase the absorption of liquid paraffin and other fat soluble substances.

PREGNANACY AND LACTATION:

The safety of this medicine in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults: One or two medicine measures (5 ml to 10 ml) three to six times a day.

Children over three years old: One medicine measure (5 ml) three to six times a day. The efficacy of this product in children under 3 years of age has not yet been proven. **EXPIGEN COUGH** syrup should be kept in the mouth for a few minutes and it should not be taken together with food or beverages.

SIDE EFFECTS:

Large doses of ammonium chloride may cause nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness and may lead to acidosis and hypokalaemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "**SIDE EFFECTS AND SPECIAL PRECAUTIONS**".

Treatment is symptomatic and supportive.

IDENTIFICATION:

Brown, clear syrup with an odour of aniseed and a taste of liquorice.

PRESENTATION:

Amber glass bottles of 100 ml and 200 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E/10.1/21

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

Adcock Ingram Limited

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