

1.3.1.1 PACKAGE INSERT

SCHEDULING STATUS: S0

PROPRIETARY NAME: DILINCT JUNIOR
(AND DOSAGE FORM) (SYRUP)

COMPOSITION:

Each 10 ml contains:

Guaifenesin	200 mg
Nipastat (preservative)	0,02 % <i>m/v</i>

In a sugar free, alcohol free, mentholated, honey flavoured base.

List of Excipients:

Caramel, flavour honey, glycerol, levomenthol, nipastat, propylene glycol, purified water, saccharin sodium, sodium cyclamate, sorbitol (70%) solution (non-crystallising), xanthan gum.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants

PHARMACOLOGICAL ACTION:

Guaifenesin has expectorant properties.

INDICATIONS:

Alleviation of cough.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Pregnancy. Porphyria.

WARNINGS:

Guaifenesin should not be taken for persistent cough such as occurs with smoking, asthma, emphysema or where cough is accompanied by excessive secretions except under the advice and supervision of a doctor.

A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur or is accompanied by high fever, rash or persistent headache, consult a doctor.

Guaifenesin should not be given to children under 2 years unless recommended by a doctor.

DOSAGE AND DIRECTIONS FOR USE:

Adults, adolescents and geriatrics: 10 ml to 20 ml (2 to 4 medicine measures) every 4 hours.

Children:

6 to 12 years: 5 ml to 10 ml (1 to 2 medicine measures) every 4 hours.

2 to 6 years: 2,5 ml to 5 ml ($\frac{1}{2}$ to 1 medicine measure) every 4 hours.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Gastrointestinal discomfort (including diarrhoea, nausea, vomiting and stomach pains). Dizziness, headache, skin rash and urticaria occurs less frequently.

Precautions: Consult a doctor if cough persists after medication has been used for 7 days or if fever, skin rash, continuing headache, or sore throat is present with cough.

Interactions: Guaifenesin interferes with urine tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Very large doses can cause nausea and vomiting.

Treatment is symptomatic and supportive.

IDENTIFICATION:

Brown, clear, viscous syrup. Odour of honey and menthol.

Taste - sweet, of honey and menthol.

PRESENTATION:

50 ml and 100 ml packed into clear or amber PVC bottles.

200 ml packed into amber PVC bottles.

100 ml packed into amber glass bottles.

STORAGE INSTRUCTIONS:

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

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

33/10.1/0086

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

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