PROFESSIONAL INFORMATION

SCHEDULING STATUS:

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1. NAME OF THE MEDICINE

DILINCT JUNIOR 200 mg syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 10 mL contains:	
Guaifenesin	200 mg

Excipients with known effects:

Preservative: Paraben Blend 0,02 % $^{m}/_{v.}$

Contains sugar alcohol: 2 mL sorbitol,

1,5 mL glycerol

Contains sweeteners: 16 mg saccharin sodium and 13 mg sodium cyclamate

Alcohol free.

Tartrazine free.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup

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

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

Alleviation of cough.

4.2 Posology and method of administration

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.

Not for use in children under 6 years of age. (See CONTRAINDICATIONS)

Method of administration: Oral administration only.

Shake the bottle before use.

4.3 Contraindications

- Hypersensitivity to guaifenesin or to any of the excipients listed in section 6.1
- Pregnancy and lactation (see section 4.6).
- Patients with acute Porphyria
- Do not use in children under 6 years of age.

4.4 Special warnings and precautions for use

- 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. Consult a doctor if cough persists after medication has been used for 7 days, tends to recur, or is accompanied by high fever, skin rash or persistent headache, or sore throat is present with cough.

- Caution should be exercised in the presence of severe renal or severe hepatic impairment
- Sodium: DILINCT JUNIOR contains less than 1 mmoL sodium (23 mg) per 5 mL, essentially 'sodium-free'.
- Propylene glycol: DILINCT JUNIOR may contains 0,25 mL propylene glycol in each 5 mL which is equivalent to 5 % v/v.
    - If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.
    - If you are pregnant or breastfeeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case by case basis.
    - If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.
- Parabens: DILINCT JUNIOR contains a paraben blend which may cause allergic reactions (possibly delayed).

- Glycerol: May cause headache, stomach upset and diarrhoea.
- This medicine contains approximately upto 1,55 mL sorbitol in each 5 mL, which is equivalent to 398,66 mg/mL. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
- The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.
- Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

4.5 Interaction with other medicines and other forms of interaction

Interactions with other medicines

None known.

Interactions with Laboratory tests

- Guaifenesin interferes with urine tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillymandellc acid (VMA)

Interactions with food, drink, alcohol

None known.

4.6 Fertility, pregnancy and lactation

DILINCT JUNIOR should not be used during pregnancy and lactation (see section 4.3).

No fertility data available

4.7 Effects on ability to drive and use machines

DILINCT JUNIOR may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned that their child's concentration may be impaired.

4.8 Undesirable effects

System Organ Class	***Frequency***	***Undesirable effect***
Immune system disorders	Less frequent	Hypersensitivity
Nervous system disorders	Less frequent	headache, drowsiness, dizziness
Gastrointestinal disorders	Less frequent	diarrhoea, nausea, vomiting, stomach pains
Skin and subcutaneous tissue disorders	Less frequent	skin rash, urticaria

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important.

It allows continued monitoring of the benefit /risk balance of the medicine.

Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Adverse Drug Reactions may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com.

4.9 Overdose

In large doses, guaifenesin will cause drowsiness, nausea and vomiting. It may also cause renal calculi. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

A 10.1 Antitussives and expectorants

ATC code: R05CA03

Guaifenesin has expectorant properties.

5.2 Pharmacokinetic properties

Absorption: Guaifenesin is well absorbed from the gastrointestinal tract following oral administration, although limited information is available on its pharmacokinetics.
After the administration of 600 mg oral liquid dose of guaifenesin to healthy adult volunteers, the Cmax was approximately 1,4 µg/mL, with Tmax occurring approximately 15 minutes after administration. The half-life was approximately 1 hour and there was no detectable levels in the blood after approximately 8 hours, indicating rapid metabolism and excretion.
Metabolism: Guaifenesin appears to undergo both oxidation and demethylation.
Excretion: Guaifenesin is excreted predominantly in the urine.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Caramel
- Honey flavour
- Glycerol [E422]
- Levomenthol
- Paraben blend
- Propylene glycol [E1520]
- Saccharin sodium [E954]
- Sodium cyclamate
- Sorbitol 70 % solution [E420]
- Xanthan gum

6.2 Incompatibilities

No information available.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 ^{o}C.

6.5 Nature and contents of container

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.

Not all pack sizes may be marketed at the same time.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK /232625.

8. REGISTRATION NUMBERS:

33/10.1/0086

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 October 2000

10. DATE OF REVISION OF THE TEXT

26 June 2026.

Botswana: S4 BOT0801461
Namibia: NS0 06/10.1/0196