

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

DILINCT JUNIOR 200 mg syrup

Each 10 mL syrup contains:

Guaifenesin 200 mg

Preservatives: 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.

Read all of this leaflet carefully because it contains important information for you.

DILINCT JUNIOR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take DILINCT JUNIOR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DILINCT JUNIOR with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if you / your child's symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What DILINCT JUNIOR is and what it is used for
2. What you need to know before you take DILINCT JUNIOR
3. How to take DILINCT JUNIOR
4. Possible side effects
5. How to store DILINCT JUNIOR
6. Contents of the pack and other information.

1. What DILINCT JUNIOR is and what it is used for

DILINCT JUNIOR contains guaifenesin (an expectorant) to help loosen mucus (phlegm) from the lungs and make it easier to cough up.

2. What you need to know before you take/ give DILINCT JUNIOR

Do not take/give DILINCT JUNIOR:

- If you or your child is hypersensitive (allergic) to guaifenesin or any of the other ingredients of DILINCT JUNIOR (see What DILINCT JUNIOR contains).
- If you are pregnant or breastfeeding (see Pregnancy, breastfeeding and fertility).
- If you or your child has acute porphyria (an inability to break down chemicals called porphyrins)
 - DILINCT JUNIOR is not recommended for use in children under the age of 6 years.

Warnings and precautions

Take special care with DILINCT JUNIOR:

- If you suffer from liver or kidney problems.
- If you or your child have a persistent or chronic cough accompanied by excessive, mucus (phlegm). You should only use DILINCT JUNIOR under the advice and supervision of your doctor.
- Consult your doctor if your or your child's cough persists for more than one week, tends to recur or is accompanied by high fever, rash or persistent headache.

Important information about some of the ingredients of DILINCT JUNIOR

- Glycerol: May cause headache, stomach upset and diarrhoea.
- DILINCT JUNIOR contains approximately upto 1,55 mL sorbitol in each 5 mL, which is equivalent to 398,66 mg/mL.
- 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.
- DILINCT JUNIOR contains less than 1 mmol sodium (23 mg) per 5 mL, essentially 'sodium-free'.
- DILINCT JUNIOR 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.
 - 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.

- 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.
- DILINCT JUNIOR contains a paraben blend which may cause allergic reactions (possibly delayed).

Other medicines and DILINCT JUNIOR

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- DILINCT JUNIOR may interfere with certain laboratory test results.

Pregnancy, breastfeeding and fertility

Do not take this syrup during pregnancy or whilst breastfeeding. No fertility data available. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking DILINCT JUNIOR.

Driving and using machines

The effects of DILINCT JUNIOR on your child's ability to concentrate may be impaired.

It is not always possible to predict to what extent DILINCT JUNIOR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DILINCT JUNIOR affects them.

3. How to take/ give DILINCT JUNIOR

Do not share medicines prescribed for you with any other person.

Always give DILINCT JUNIOR syrup exactly according to instructions. You should check with a doctor or pharmacist if you are unsure.

Always give DILINCT JUNIOR exactly as described in this leaflet or as your health care professional has told you. Check with your health care professional if you are not sure.

The usual dose is:

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 Do not take/give DILINCT JUNIOR)

Oral administration only.

Shake the bottle before use.

DILINCT JUNIOR can be taken with or without food.

If you have the impression that the effect of DILINCT JUNIOR is too strong or too weak, tell your doctor or pharmacist.

If you give/ take more DILINCT JUNIOR than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center immediately. Take this leaflet

and the rest of the remaining syrup with you so the doctor will know what you have taken. Should your child or somebody else have taken an overdose of DILINCT JUNIOR, the following symptoms may be experienced: nausea (feeling sick), vomiting (being sick), severe stomach pain and drowsiness

If you forget to use DILINCT JUNIOR

If you forget to take or give a dose, take or give the next dose when needed provided that the last dose was at least 4 hours ago. Do not take or give a double dose to make up for the forgotten individual doses.

4. Possible Side Effects

DILINCT JUNIOR can have side effects.

Not all side effects reported for DILINCT JUNIOR are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking DILINCT JUNIOR, please consult your health care provider for advice.

If any of the following happens, stop using DILINCT JUNIOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;

- rash, hives or itching;
- fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to DILINCT JUNIOR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring less frequently:

- headache or dizziness;
- drowsiness;
- diarrhoea, nausea (feeling sick), vomiting (being sick), pain in your stomach.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DILINCT JUNIOR.

5. How to store DILINCT JUNIOR

Keep all medicines out of the reach and sight of children.

Store in a safe place at or below 25 °C.

Keep well closed and store in a cool place

Do not use after the expiry date on the label.

Do not dispose of unused medicines in drains or sewerage systems.

6. Contents of the pack and other information

What DILINCT JUNIOR contains:

Each 10 mL contains:	
Guaifenesin	200 mg

The other ingredients are caramel, honey flavour, glycerol [E422], levomenthol, paraben blend, propylene glycol [E1520], saccharin sodium [E954], sodium cyclamate, sorbitol 70 % solution [E420] and xanthan gum

What DILINCT JUNIOR looks like and contents of the pack

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

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.

Holder of Certificate of Registration

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This leaflet was last revised on

26 June 2026.

Registration number

33/10.1/0086

Botswana: S4 BOT0801461

Namibia: NS0 06/10.1/0196
