

Package leaflet: Information for the patient

Nipenesin 200 mg syrup in sachet guaifenesin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You or the adolescent must talk to a doctor if you or the adolescent do not feel better or if you feel worse after 5 days

What is in this leaflet:

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

1. What <Invented name> is and what is it used for

<Invented name> contains guaifenesin and is used to help relieve chesty coughs in adults and adolescents aged 12 years and over.

<Invented name> help loosen mucus (phlegm) from the lungs and make it easier to cough up.

2. What you need to know before you take this <Invented name>

Do not take <Invented name>

- if you are allergic to guaifenesin or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking <Invented name> if you:

- have had a cough or if you feel worse for more than 5 days or your cough recurs or is accompanied by a fever, rash, or persistent headache.
- have a persistent cough that may be caused by asthma.
- have a cough which brings up a lot of mucus (phlegm).
- have severe liver or kidney problems.
- have epilepsy since the product contains alcohol (see <Invented name> contains ethanol, glucose, sucrose, sodium benzoate, sodium and propylene glycol).

Children and adolescents

This medicine should not be used in children under 12 years of age.

Other medicines and <Invented name>

Tell a pharmacist if you are taking, have recently taken, or might take any other medicines since it can affect or be affected by other medicines.

Do not take this medicine with other cough medicines intended to stop you from coughing as they may interfere with the action of this medicine.

Some urine tests may be affected if taken within 24 hours of taking this medicine. Tell the doctor or nurse taking the urine sample that you are taking this medicine.

<Invented name> with food and drink

This medicinal product contains alcohol (see section <Invented name> contains ethanol, glucose, sucrose, sodium benzoate, sodium and propylene glycol).

Pregnancy breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask a doctor or pharmacist for advice before taking this medicine.

Fertile women

This medicine should not be used by women of childbearing potential not using contraception.

Pregnancy

This medicine should not be used during pregnancy.

Breast-feeding

Do not take this medicine if you are breast-feeding until you speak with a doctor, as guaifenesin may be passed to your baby in your breast milk.

Driving and using machines

It is not expected that this product will affect your ability to drive or operate machinery. However, if you do feel unwell, do not drive or use machinery.

<Invented name> contains ethanol, glucose, sucrose, sodium benzoate, sodium and propylene glycol

Ethanol

This medicine contains 400 mg of alcohol (ethanol) in each sachet which is equivalent to 4g/dl (4 % w/v). The amount in each sachet of this medicine is equivalent to 10 ml beer or 4 ml wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

Glucose and sucrose

This medicine contains glucose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains approximately 7 g glucose and 2 g sucrose per sachet. This should be taken into account in patients with diabetes mellitus.

Sodium benzoate

This medicine contains 10 mg benzoate salt in each sachet which is equivalent to 1 mg/ml.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

Propylene glycol

This medicine contains 79 mg propylene glycol in each sachet which is equivalent to maximum 7.9 mg/ml.

3. How to take this <Invented name>

Always take this medicine exactly as described in this leaflet or as doctor or pharmacist has told you. Check with a pharmacist if you are not sure.

How to take the medicine:

Tear off the top of the sachet and dispose the top. Once open, pour the syrup directly in the mouth and swallow the syrup.

How much to take:

Recommended dose for adults and adolescents (12 years and over) is:

One 10 ml sachet, 4 times a day.

Maximum daily dose is 4 sachets (40 ml) per day (24 hours)

You or the adolescent must talk to a doctor if you or the adolescent do not feel better or if you feel worse after 5 days

If you take more <Invented name> than you should

If you or the adolescent have taken more <Product name> than you should, or if children have taken medicine by accident, always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

Symptoms of an overdose may include stomach pain, nausea and drowsiness. If you take too much of this medicine, you may develop kidney stones.

If you forget to take this <Invented name>

Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicine, ask a doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop using the <Invented name> and seek medical help immediately:

Severe allergic reactions (anaphylactic reactions) with symptoms such as:

- difficulty in breathing
- swelling of the face, neck, tongue, or throat

Allergic reactions including skin rashes (which may be severe and include blistering and peeling

of the skin) hives and itching (frequency not known).

Other side effects that may occur include:

Not known (frequency cannot be estimated from the available data)

- Stomach pain
- Nausea
- Vomiting
- Diarrhoea

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store this <Invented name>

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the sachets and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains:

The active substance is guaifenesin.
Each 10 ml sachet contains 200 mg guaifenesin

The other ingredients are: sodium citrate (E331), citric acid monohydrate, carbomer, glycerol (E422), ethanol, glucose liquid, sucrose, sucralose (E955), sodium benzoate (E211), levomenthol, caramel (E150), purified water.

Flavours: honey-, lemon-, cooling-, bitterness blocking-, tingling-, hot mix- and non-alcohol enhancer flavour. Flavours contain propylene glycol and other flavouring ingredients.

What <Invented name> looks like and contents of the pack

<Invented name> is a clear yellow-brown coloured syrup packaged in 10 ml sachets. The sachet is composed of PET, Aluminium and PE.

Carton contain: 12 or 20 sachets.
Not all pack sizes may be marketed.

Marketing authorisation holder:

{to be completed nationally}

Manufacturer:

{to be completed nationally}

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name
Sweden	Nipenesin
Belgium	Bronchosedal Mucus Honing & Citroen Unidose 200 mg, siroop in zakje
Denmark	Benysine
Ireland	Guaifenesin 200mg syrup in sachet
Luxembourg	Bronchosedal Mucus Miel & Citron Unidose 200 mg, sirop en sachet

This package leaflet was last revised in 2021-07-27.