

Mucodyne 250mg/5ml Paediatric Syrup

Carbocisteine

sanofi

Is this leaflet hard to see or read?

Phone 0800 035 2525 for help

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child.
- If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Mucodyne Paediatric Syrup is and what it is used for

Mucodyne 250mg/5ml Paediatric Syrup (called Mucodyne Paediatric Syrup in this leaflet) contains a medicine called carbocisteine. This belongs to a group of medicines called 'mucolytics'.

It works by making mucus (phlegm) less sticky. This makes the mucus easier to cough up.

Mucodyne Paediatric Syrup is used for problems with the breathing passages (respiratory tract). These problems happen when too much mucus is made, or the mucus is too sticky.

2. What you need to know before you use Mucodyne Paediatric Syrup

Do not use this medicine and tell your child's doctor if:

- ✗ Your child is under 2 years of age.
- ✗ Your child is allergic (hypersensitive) to carbocisteine or any of the other ingredients of Mucodyne Paediatric Syrup (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.

- ✗ Your child has an ulcer in their stomach or gut (small intestine).

Do not use this medicine if any of the above apply to your child. If you are not sure, talk to your child's doctor or pharmacist before using Mucodyne Paediatric Syrup.

Warnings and Precautions

Talk to your child's doctor before using this medicine if:

- ▲ Your child has had an ulcer in their stomach or gut.
- ▲ Your child is taking other medicines known to cause bleeding in the stomach.

Mucodyne Paediatric Syrup contains

- **Sucrose:** This medicine contains 2g of sucrose per 5ml. This may be harmful to the teeth and should be taken into account in patients with diabetes mellitus. If you have been told by your child's doctor that your child cannot tolerate some sugars, talk to your child's doctor before using this medicine.
- **Ethanol:** This medicine contains a small amount of ethanol (alcohol), less than 67.2mg per 5ml. The amount in 5ml of this medicine (contained in the aromatic elixir flavouring as an ingredient necessary for the medicine to work properly) is equivalent to less than 1.7ml beer or 0.68ml wine. Although it is a small amount, the alcohol in the maximum daily dose of this preparation is likely to affect children. These effects may include feeling sleepy and changes in behaviour. It may also affect their ability to concentrate and take part in physical activities. If your child has epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine. The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if your child is taking other medicines.
- **Sodium:** This medicine contains 33mg of sodium per 5ml. This is equivalent to 3% of the recommended maximum daily dietary intake of sodium for a child over 4 years and 4% of the recommended maximum daily dietary intake of sodium for a child over 2 years. Take this into consideration if your child is on a controlled sodium diet.
- **Methyl parahydroxybenzoate:** May cause allergic reactions (possibly delayed).

3. How to use Mucodyne Paediatric Syrup.

Always use Mucodyne Paediatric Syrup exactly as your child's doctor has told you. You should check with your child's doctor or pharmacist if you are not sure.

Using this medicine in children

- Give this medicine to your child by mouth.
- The amount of medicine will depend on the age of the child.
- If you feel the effect of your child's medicine is too weak or too strong, do not change the dose yourself, but ask your child's doctor.

How much to use

Mucodyne Paediatric Syrup 125ml pack size (only for use in children) comes with a graduated oral dosing syringe for measuring the correct dose.

The syringe for oral administration is graduated per 0.25ml. One graduation, 0.25ml, corresponds to 12.5mg/ml of carbocisteine.

Children 2 – 5 years:

1.25–2.5ml four times a day.

Children 5 – 12 years:

5ml three times a day.

How to use the syringe – using the 5ml easy dosing syringe

Step 1: The syringe end should be placed into the neck of the bottle below the liquid fill line.

Step 2: To fill the syringe whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. The dose for children is given above based on age.

Step 3: Remove the syringe from the bottle neck carefully.

Step 4: Place the end of the syringe into the child's mouth against the cheek and carefully press the plunger down slowly to gently release the medicine. After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of the sight and reach of children.

If your child takes more Mucodyne Paediatric Syrup than they should

If your child takes more Mucodyne Paediatric Syrup than they should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what your child has taken. If your child takes too much Mucodyne Paediatric Syrup it is likely that they will get an upset stomach (gastrointestinal disturbance).

If you forget to use Mucodyne Paediatric Syrup

If you forget a dose, do not worry. Just wait until the next dose is due. **Do not** use a double dose to make up for a forgotten dose.



If you have any further questions on the use of this medicine, ask your child's doctor or pharmacist.

4. Possible side effects

Like all medicines, Mucodyne Paediatric Syrup can cause side effects, although not everybody gets them.

Stop using Mucodyne Paediatric Syrup and see a doctor or go to a hospital straight away if:

- Your child has an **allergic reaction**. The signs may include: a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- Your child has blistering or bleeding of the skin, including around their lips, eyes, mouth, nose and genitals. They may also have flu-like symptoms and fever. This may be something called 'Stevens-Johnson Syndrome'.
- Your child has blood in their vomit or black tarry stools.

Tell your child's doctor or pharmacist if any of the following side effects get serious or last longer than a few days:

- Feeling sick (nausea) or being sick (vomiting)
- Diarrhoea
- Stomach pain

Reporting of side effects

If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card on the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mucodyne Paediatric Syrup

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

Do not use Mucodyne Paediatric Syrup after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month. After use, wipe the neck of the bottle with a clean, damp cloth. This will remove any medicine left on the bottle, so you can put the cap back on tight. If you use the oral dosing measuring syringe for Mucodyne Paediatric Syrup to give this medicine, make sure the measuring device is clean and dry before use.

Store below 25°C.

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 Mucodyne Paediatric Syrup contains

- Each 5ml of Syrup contains 250mg of the active substance, carbocisteine.
- The other ingredients are methyl parahydroxybenzoate (E218), sucrose, caramel (E150), aromatic elixir flavour (contains ethanol), cinnamon flavour, sodium hydroxide and purified water.

What Mucodyne Paediatric Syrup looks like and contents of the pack

Mucodyne Paediatric Syrup is a clear amber coloured syrupy liquid.

Mucodyne Paediatric Syrup for children is available in 125ml bottles sealed with a child-proof cap and comes with a graduated dosing syringe.

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about this medicine. If you have any questions or are not sure about anything, ask your child's doctor or pharmacist.

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