

## **Mucotex 250 mg/5 ml syrup carbocisteine**

### **Package leaflet: Information for the user**

**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 has 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 must talk to a doctor if you do not feel better or if you feel worse.

### **WHAT IS IN THIS LEAFLET**

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

#### **1. What Mucotex Syrup is and what it is used for**

Mucotex 250 mg/5 ml syrup (called Mucotex Syrup in this leaflet) contains a medicine called carbocisteine. This belongs to a group of medicines called “mucolytics” used in the antibacterial treatment of respiratory infections, in the presence of bronchial hypersecretion. It works by making the mucus (catarrh) less sticky. This makes the mucus easier to exit when coughing.

Mucotex Syrup is used for problems in the airways when there is too much mucus or when it is too sticky.

You must talk to your doctor if you do not feel better or if you feel worse.

#### **2. What you need to know before you take Mucotex Syrup**

##### **Do not take Mucotex Syrup:**

- if you have a gastroduodenal ulcer;
- if you are allergic to carbocisteine or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Mucotex Syrup:

- Asthmatic patients and with a history of bronchospasm,
- Severe respiratory insufficiency,
- Debilitated patients. Due to the decrease of the cough reflex, there is risk of obstruction of the airway as a consequence of the increase of the quantity of secretions.

The use of Mucotex Syrup implies a decrease of the mucus viscosity and its removal, either through the ciliary activity of the epithelium, either through the cough reflex, therefore an increase of the expectoration and cough should be expected. Do not associate this medicine with an antitussive. Mucolytics, as they have the ability to destroy the gastric mucosa barrier, should be used with caution in individuals susceptible to gastroduodenal ulcers.

### **Children**

This medicine is not indicated in children aged less than 2 years.

### **Other medicines and Mucotex Syrup**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should not take cough calming or secretion-drying medicines, because these have an effect contrary to that of carbocisteine.

### **Pregnancy and breast-feeding**

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

*Pregnancy:*

It is not recommended to use in the pregnant woman, especially during the first 3 months of pregnancy, even though no teratogenic effects have been detected.

*Breastfeeding:*

It is not recommended to use during breastfeeding because there are no safety data, concerning the passage of carbocisteine into breast milk. Considering its low toxicity, if the mother is treated with this product, the potential risks for the child seem negligible.

### **Driving and using machines**

No effects were seen on the ability to drive and use machines.

### **Mucotex Syrup contains Sucrose**

For use in children

This medicine contains 2.9 g of sucrose in each 5 ml paediatric dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

For use in adults

This medicine contains 8.7 g of sucrose in each 15 ml adult dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Mucotex Syrup contains methyl parahydroxybenzoate (E218).**

May cause allergic reactions (possibly delayed).

## **3. How to take Mucotex Syrup**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. Using the measuring device (oral syringe with 5 ml capacity), measure the quantity that you will need whether you are an adult or a child, according to the general posology. The syringe for oral administration is graduated per 0.25 ml. One graduation, 0.25 ml corresponds to 12.5 mg/ml of carbocisteine.

*How to use the syringe:*

Step 1: Check the measurements on the side of the syringe to see how much to fill it.

Step 2: Push the syringe's plunger all the way down. Then put the tip of the syringe into the medicine bottle.

Step 3: Slowly pull back on the plunger until the syringe fills to the appropriate mark. Make sure there are not any large air bubbles in the syringe. If there are, empty the syringe and try again.

Step 4: Place the end of the syringe into the 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 reach of children.

#### **Use in adults**

The usual dose for adults is 15 ml, 3 times daily. If your symptoms improve, your dose may be lowered to 10 ml, 3 times daily.

#### **Use in children and adolescents**

This medicine is not indicated in children aged less than 2 years.

From 2 to 5 years old: 1.25 ml to 2.5 ml, 4 times daily.

From 6 to 12 years old: 5 ml, 3 times daily in evenly spaced intervals.

After using the syrup, close the bottle well.

#### **If you take more Mucotex Syrup than you should**

If upset stomach, nausea and vomiting occur, you should stop taking Mucotex Syrup and see the doctor.

#### **If you forget to take Mucotex Syrup**

If it is almost time to take the next dose, only take the next dose. If not, take the forgotten dose as soon as you remember.

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

#### **If you stop taking Mucotex Syrup**

Not applicable.

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

#### **4. Possible side effects**

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

##### *Uncommon:*

Digestive changes: nausea, vomiting and diarrhoea.

##### *Rare:*

Hypersensitivity reactions, as hives and bronchospasm. Special attention in the asthmatic patients due to the risk of occurring bronchoconstriction (contraction of a muscle of the bronchial wall that leads to a reduction in the air passage). In these cases, the treatment should be stopped.

Headache, muscle pain, dizziness, urinary incontinence, palpitations and breathlessness.

*Not known*

Allergic reactions, such as skin rash. Special attention in the patients with compromised thyroid function due to the risk of occurring hypothyroidism.

Gastric discomfort, bronchorrhea (increased bronchial secretion).

### **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 to HPRA

Pharmacovigilance:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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

## **5. How to store Mucotex Syrup**

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

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

Do not store above 25°C.

Once the bottle is opened, Mucotex Syrup must be used within 3 months.

If your syrup appears to be discoloured or shown any other signs of deterioration, take it back to your pharmacist who will advise you.

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 Mucotex Syrup contains**

The active substance is carbocisteine. Each 5 ml of syrup contains 250 mg carbocisteine.

The other ingredients are: sucrose, caramel (E150), gooseberry flavour, sodium hydroxide (for pH-adjustment), methyl parahydroxybenzoate (E218) and purified water.

### **What Mucotex Syrup looks like and contents of the pack**

Carbocisteine is presented as a yellow-amber liquid with gooseberry flavour and a sweet taste. 200 ml or 300 ml bottles, of type III amber glass, with measuring device (oral syringe with 5 ml capacity).

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Amdeepcha (Malta) Ltd

527 Saint Paul's Street,

St Paul's Bay SPB 3148,

Malta

**Manufacturer**

Laboratórios Basi – Indústria Farmacêutica, S.A.  
Parque Industrial Manuel Lourenço Ferreira, Lotes 8, 15 e 16  
3450-232 Mortágua, Portugal  
Tel.: +351 231 920 250  
Fax: +351 231 921 055  
E-mail: basi@basi.pt

**This leaflet was last revised in 04/2022.**