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Package Leaflet: Information for the user
Viscolex Syrup 250 mg / 5 ml Oral Solution
Carbocisteine

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

1. What Viscolex Syrup is and what it is used for

Viscolex Syrup is used to help treat lower respiratory tract disorders (disorders of the breathing passages) where the lungs produce too much mucus or the mucus is too thick. It contains carbocisteine which is a mucolytic agent that is used to dissolve and break down thick mucous in conditions such as chronic asthma or bronchitis.

2. What you need to know before you take Viscolex Syrup

Do not take Viscolex Syrup:

- If you are allergic to carbocisteine or any of the other ingredients of this medicine (listed in section 6).
- If you have an active peptic ulcer.
- Do not give to children under 2 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Viscolex Syrup:

- If you are an older patient
- If you have a history of gastrointestinal ulcers
- If you are taking medication known to cause gastrointestinal bleeding
- If you have a history of peptic ulcer
- If you are on a low sodium diet
- If you have a rare hereditary fructose intolerance or an intolerance to some sugars.

Other medicines and Viscolex Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Viscolex Syrup with food and drink

Food and drink has no known effect when taken with this product.

Pregnancy and breast-feeding

This product should not be used during pregnancy or breast-feeding unless considered essential by a physician. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Viscolex Syrup has no known effect on your ability to drive or use machines.

Viscolex Syrup contains sunset yellow, sucrose, orange flavour, parahydroxybenzoates and sodium

- **Sunset yellow (E110);** this may cause allergic reactions.
- **Sucrose;** If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. When taken according to dosage recommendations the maximum daily dose supplies up to 27 g of sucrose.
- **Orange flavour;** this contains small amounts of ethanol (alcohol), less than 15 mg per 5 ml dose.
- **Parahydroxybenzoates (E215, E217, E219);** these may cause allergic reactions (possibly delayed).
- **Sodium content:** This medicinal product contains 38mg of sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Viscolex Syrup

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. For Oral Use. The recommended dose is:

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Adults:	Three 5 ml spoonfuls three times daily initially, then reducing to two 5 ml spoonfuls three times daily when a satisfactory response has been obtained.
Children 6-12 years:	One 5 ml spoonful two or three times daily.
Children 2-5 years:	Half a 5 ml spoonful three times daily.
Children under 2 years:	Not recommended.

If you take more Viscolex Syrup than you should

Contact your doctor or pharmacist who will recommend what action you should take.

If you forget to take Viscolex Syrup

If you miss a dose, take it as soon as you remember and take any remaining doses for that day at evenly spaced intervals. **Do not** take a double dose to make up for a forgotten dose.

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.

The following convention has been utilised for the classification of undesirable effects: very common ($\geq 1/10$), common ($\geq 1/100 < 1/10$), uncommon ($\geq 1/1,000 < 1/100$), rare ($\geq 1/10,000 < 1/1,000$), very rare ($< 1/10,000$), unknown (cannot be estimated from the available data).

If you notice any of the following serious side effects, stop taking Viscolex Syrup and contact a doctor immediately:

- Allergic reaction with swelling of the skin or face or extremities, swelling of lips or tongue, swelling of the mucous membranes in the mouth and throat, resulting in shortness of breath and difficulty to swallow (angioedema).
- You have blistering or bleeding of the skin, including around your lips, eyes, mouth, nose and genitals. You may also have flu-like symptoms and fever. This may be something called 'Stevens-Johnson syndrome'.

Nervous System disorders

Unknown: Headache

Gastrointestinal disorders

Unknown: Nausea, upset stomach, diarrhoea, gastro-intestinal bleeding, vomiting

Skin and subcutaneous tissue disorders

Unknown: skin rash, and allergic skin outbreaks such as erythema multiforme.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Viscolex Syrup

Keep out of the sight and reach of children. Do not store above 25°C. Keep container tightly closed. Do not use this medicine after the expiry date which is stated on the label. 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 to protect the environment.

6. Contents of the pack and other information

What Viscolex Syrup contains:

- The **active substance** is carbocisteine 250 mg / 5 ml.
- The **other ingredients** are: Sucrose, Sunset Yellow Colouring (E110), Sodium Methyl Parahydroxybenzoate (E219), Sodium Ethyl Parahydroxybenzoate (E215), Sodium Propyl Parahydroxybenzoate (E217), Disodium Edetate, Sodium Hydroxide, Glycerol (E422), Orange Flavour (contains ethanol <15 mg / 5 ml), Citric Acid Monohydrate and Purified Water. [See end of section 2 for other important information on other ingredients].

What Viscolex Syrup looks like and contents of the pack:

It is a clear, yellow, oral solution with odour and flavour of orange. It is packed in amber glass bottles containing 100 ml or 250 ml of solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Limited, Ballymacarbray, Clonmel, Co. Tipperary.

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