PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER Ambroxol Hydrochloride, Salbutamol Sulfate, Guaifenesin and Levomenthol Syrup MUCOLEX

Read all of this leaflet carefully before you starts giving 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 doctor, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist

In this leaflet:

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

1. WHAT AMBROXOL HYDROCHLORIDE, SALBUTAMOL SULFATE, GUAIFENESIN AND LEVOMENTHOL SYRUP- MUCOLEX ARE AND WHAT THEY ARE USED FOR

Mucolex is indicated in adults, adolescents and children aged 2 to 12 years for symptomatic relief in treatment of productive cough associated with various respiratory disorders like acute bronchitis, acute exacerbation of chronic bronchitis(AECB), Pneumonia, asthamatic bronchitis etc

2. What you need to know before you take AMBROXOL HYDROCHLORIDE, SALBUTAMOL SULFATE, GUAIFENESIN AND LEVOMENTHOL SYRUP -MUCOLEX

Do not take MUCOLEX:

• Eclampsia and severe pre-eclampsia; intra-uterine infection, intra-uterine foetal death, antepartum haemorrhage, placenta praevia and cord compression, threatened miscarriage, cardiac disease. Hypersensitivity to the active substance or any of the excipients listed herewith.

Other medicines and MUCOLEX

Diuretics, corticosteroids and xanthines may augment hypokalaemia. CV effects potentiated by MAOIs, TCAs, sympathomimetics. Increases absorption of sulfamethoxazole when used together. May markedly increase heart rate and BP when used with atomoxetine. Reduces serum levels of digoxin. Hypokalaemia induced by salbutamol increases the risk of digitalis toxicity. BP should be closely monitored if linezolid is used concurrently with salbutamol.

MUCOLEX with food and drink

Not applicable.

Pregnancy and breast-feeding

Pregnancy

Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Breast-feeding

Avoid usage in lactating mothers.

Mild to moderate pre-eclampsia. Arrhythmias, hyperthyroidism, hypertension, DM, myocardial insufficiency, susceptibility to QT-interval prolongation. Monitor serum potassium levels. In women treated for premature labour, monitor hydration status, cardiac and respiratory function. Minimise volume of infusion fluid. Discontinue treatment if patient develops signs of pulmonary oedema.

Driving and using machines

No effects have been reported.

3. How to take AMBROXOL HYDROCHLORIDE, SALBUTAMOL SULFATE, GUAIFENESIN AND LEVOMENTHOL SYRUP -MUCOLEX

Children 2 to 6 years= 2.5ml three times a day

- Children 6 to 12 years= 5ml two to three times a day
- Children 12 years and above and Adults= 5ml three times a day or 10ml two times a day OR

As directed by physician.

If you take more MUCOLEX than you should

May lead to tachycardia, tremor, CNS stimulation, hypokalaemia and hyperglycaemia. Symptomatic treatment is recommended.

If you forget to take MUCOLEX

No effects have been reported

If you stop taking MUCOLEX

No effects have been reported

4. Possible side effects

No effects have been reported

5. How to store AMBROXOL HYDROCHLORIDE, SALBUTAMOL SULFATE, GUAIFENESIN AND LEVOMENTHOL SYRUP -MUCOLEX

Do not store above 30°C. Protect from light. Shake well before use

Keep the medicine out of reach of children.

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 protect the environment.

6. Contents of the pack and other information

What MUCOLEX contains:

Active Pharmaceutical Ingredients are:

Ambroxol Hydrochloride ,Salbutamol Sulfate, Guaifenesin ,Levomenthol

Excipients are:

Citric acid monohydrate, Disodium Edetate, Sodium Benzoate, Potassium Sorbate, Sugar S-30, Propylene Glycol, Glycerol, Sorbitol 70% (Non-crystallizing), Colour Sunset Yellow FCF Supra, Flavour Raspberry ASV, Flavour Sweet Orange RSWL

What AMBROXOL HYDROCHLORIDE, SALBUTAMOL SULFATE, GUAIFENESIN AND LEVOMENTHOL SYRUP- MUCOLEX looks like and contents of the pack:

MUCOLEX is Orange coloured clear liquid..

They are packaged in 100 ml amber coloured glass bottle packed in a printed carton with a printed insert.

Manufactured by:



1802-1805, G.I.D.C., Phase III, Vapi - 396 195. Gujarat, INDIA.