

## Exall Forte®

Sugar Free Syrup  
Chlorpheniramine Maleate/Diprophylline/Guaifenesin/  
Acetaminophen

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 doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet?

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

#### 1. What Exall Forte® syrup is and what it is used for

This medicine combines between chlorpheniramine, an antihistamine, diprophylline, with bronchodilator action, guaifenesin, an expectorant that loosens mucus viscosity and thin bronchial secretion, and acetaminophen, which reduces pain and fever.

It is indicated for the relief of pain, fever, bronchospasm associated with cold, flu and allergies and loosens stubborn mucus (phlegm) and provide relief from chesty coughs.

#### 2. What you need to know before you take Exall Forte® syrup

- Do not take Exall Forte® syrup:
- If you are allergic (hypersensitive) to any of the ingredients of Exall Forte® syrup.
  - If you suffer from liver disease (with or without liver failure) or viral hepatitis (increased risk of hepatotoxicity).
  - If you are hypersensitive to xanthine bases.
  - Do not use this medicine in children under 2 years old.
- Take special care with Exall Forte® syrup:
- Do not take more than the recommended dose.
  - In Chronic Alcoholism, do not take more than 2g/day of Acetaminophen (120 ml Exall Forte® syrup).

- In patients with kidney, heart or lung disease and patients with anemia.
- In asthmatic patients sensitive to acetylsalicylic acid.
- In patients who are hypersensitive to an antihistamine because they could be sensitive to other antihistamines (such as Chlorpheniramine).
- In patients with glaucoma, peptic ulcer and diabetes.
- In patients with severe hypertension, prostatic hypertrophy, bladder neck obstruction, urinary retention and hyperthyroidism.

Use with other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These instructions are as well for medicines you have used before or you will use in the future.

Interactions due to Acetaminophen:

- Antibiotics (chloramphenicol).
- Oral anticoagulants (acenocoumarol, warfarin).
- Oral contraceptives and estrogens treatments.
- Antiepileptics (lamotrigine, phenytoin or others hydantoin, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Medicines for tuberculosis (isoniazid, rifampicin).
- Barbiturates (used as hypnotics, sedatives and anticonvulsants).
- Activated Carbon (adsorbent).
- Cholestyramine (to reduce blood cholesterol levels).
- Medicines used for gout (Probenecid and Sulphinpyrazone).
- Some medicines to increase urine excretion (Loop diuretics such as furosemide group).
- Medicines used to relief stomach, gut and bladder cramps (anticholinergic).
- Medicines used for heart (digitalis glycosides).
- Metoclopramide and domperidone (for nausea and vomiting).
- Propranolol used to treat high blood pressure (hypertension and cardiac arrhythmias).
- Zidovudine (medicine used to treat patients infected with the human immunodeficiency virus, which causes AIDS)

Interactions due to Chlorpheniramine:

Taking the below medicines concomitantly can increase the side effects of Exall Forte® syrup:

- Medicines that causes depression on the central nervous system (such as medicines used for insomnia or anxiety).
- Monoamine Oxidase Inhibitors (MAOI) (medicines for depression or others).
- Tricyclic and Tetracyclic antidepressants

Interactions due to Diprophylline:

- Alkalizing, sympathomimetics, and other xanthines: action of Diprophylline is enhanced and its toxicity is increased.
- Allopurinol, probenecid, pyrazolones and oral anticoagulants actions are antagonized by Diprophylline.

Interference with analytical test:

Inform your doctor if you are going to have any laboratory test (such as blood test, urine test, skin test which use allergens, etc) and you are taking or have recently taken Exall Forte® syrup because it can alter the results of these laboratory test.

Using Exall Forte® syrup with food and drink:

The use of Acetaminophen in patients who drink alcohol frequently (three or more alcoholic drinks: beer, wine, liquor... daily) is harmful for the liver. Do not take alcohol during the treatment with Exall Forte® syrup because it could produce symptoms of overdose such an increase of sedative effects.

Use in children:

Do not use in children under 2 years of age.

Use in elderly:

Do not use without consulting your doctor. Because this medicine contains Chlorpheniramine, elderly patients may be particularly affected by some adverse events such as bradycardia or reduced cardiac rate. Blood pressure should be monitored, especially in patients with heart disease (see section 4. Possible Side Effects). Also the elderly might experience side effects such as sedation, confusion, hypotension and excitability, dry mouth and urinary retention.

Pregnancy and breast-feeding:

Consult your doctor or pharmacist before taking any medicine. Inform your doctor or pharmacist if you are pregnant or planning on becoming pregnant. Pregnant women should not use Exall Forte® syrup unless it was justified by your doctor. Acetaminophen and Chlorpheniramine are known to pass into breast milk. Avoid breastfeeding while taking this medicine.

Driving and using machines:

Some patients feel visual disturbances, dizziness or drowsiness when taking this medicine. It is recommended not to drive or use machinery until you know how this medicine affects you.

Important information about some of the ingredients of Exall Forte® syrup

This medicine contains Saccharin and Sorbitol. If your doctor has made the diagnosis that you are intolerant to certain sugar substitutes, consult him before taking this medicine. This medicine contains 5% of ethanol (alcohol). This medicine is harmful for those suffering from alcoholism. Caution: to be

taken into account in pregnant women, children and high risk groups such as patients with liver disease or epilepsy.

#### 3. How to take Exall Forte® syrup

Follow these instructions unless your doctor has given you different directions. Your doctor should tell you the duration of the treatment with Exall Forte® syrup.

Posology

- Exall Forte® syrup is not recommended for children under 2 years old.
  - Children over 2 years old: 5 mL, 2 to 3 times daily.
  - Adults: 10 mL, 4 to 5 times daily.
- Oral administration only.

Duration of the treatment

Take this medicine only if you have painful symptoms or fever. When these symptoms disappear, stop the treatment. If fever lasts during more than 3 days of treatment, pain or the rest of symptoms during more than 5 days, or the symptoms worsen or new ones appear, it is recommended to consult your doctor or pharmacist.

If you take more Exall Forte® syrup than you should

Consult your doctor or pharmacist immediately. If you take an overdose of Acetaminophen, you should head quickly to the nearest hospital emergency room even if you do not have symptoms, since these symptoms frequently appear 3 days after ingestion, even in cases of severe poisoning. Symptoms of acetaminophen overdose symptoms may include: dizziness, vomiting, loss of appetite, yellowing of skin and eyes (jaundice) and abdominal pain. Treatment of overdose is more efficient if started within 4 hours of the medicine ingestion. Patients taking barbiturates or those suffering from alcoholism are more susceptible to toxicity from Acetaminophen overdose.

If you forget to take Exall Forte® syrup

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose of Exall Forte® syrup, take it as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose and go back to your regular schedule.

If you have any further question about this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, Exall Forte® syrup can have side-effects although not everybody gets them.

Side Effects Due to Chlorpheniramine

- More frequent: slight drowsiness, dizziness, muscle weakness (normally these symptoms disappear after 3 days of treatment),

difficulty in movement of the face, clumsiness, tremor, alterations of sensations and tingling, dry mouth, loss of appetite, changes in taste and smell, gastrointestinal disturbances which can be reduced if the medicine is given with food (nausea, vomiting, diarrhea, constipation, stomach pain), urine retention, dry nose and throat, thickening of mucus, sweating, blurred vision or other vision disorders.

- Less frequent or rare: occasionally paradoxical excitation (generally with high doses and more frequently with the elderly and children) with symptoms as restlessness, insomnia, nervousness and convulsions.
- Rarely: blood disorders (changes in complete blood count as agranulocytosis, leukopenia, aplastic anemia, thrombocytopenia with symptoms such as unusual bleeding, sore throat or tiredness, low or high blood pressure, edema (swelling), ears' alterations, impotence and menstrual disorders).
- Other side effects: chest tightness, noise in the lungs, fast or irregular heartbeat (generally in cases of overdose), liver disease (which may present with stomach pain, dark urine or other symptoms at the same time), allergic reaction, severe hypersensitivity reactions (cough, difficulty swallowing, fast heartbeat, itching, swelling of eyelids, face or tongue, breathing difficulty, etc), photosensitivity, cross-sensitivity (allergy) to drugs related to Chlorpheniramine.

Side Effects due to Acetaminophen

- At least 1 out of 10,000 patients: kidney disorders, dark urine, allergic dermatitis (skin rash), jaundice (coloring of the skin), blood disorders (agranulocytosis, leukopenia, neutropenia, thrombocytopenia, haemolytic anemia) and hypoglycemia (low blood sugar). Acetaminophen can damage the liver when it is taken in high doses or for long periods of time.

If you notice any serious side-effects or you notice any side-effects not included in this leaflet, consult your doctor or pharmacist.

#### 5. How to store Exall Forte® syrup

Keep Exall Forte® syrup out of the reach and sight of children. Do not use Exall Forte® syrup after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Store in the original package. Do not store above 25°C. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

Exall Forte® syrup contains:

Active ingredients: Chlorpheniramine, Guaifenesin, Diprophylline and Acetaminophen.  
Each dose of 5 ml of syrup contains:  
Chlorpheniramine maleate.....2.5 mg  
Diprophylline .....25 mg  
Guaifenesin .....100 mg  
Acetaminophen ..... 100 mg  
Other ingredients: Methyl paraben, propyl paraben, saccharin sodium, Sorbitol, ethyl alcohol, propylene glycol, polyethylene glycol 400, glycerin, pineapple flavor, cherry flavor and lime flavor.

What Exall Forte® syrup looks like and content of the pack  
Exall Forte® syrup is an oral colorless clear solution, presented in amber glass bottles of 120 ml of syrup, sealed with child-proof closures.

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:  
Algorithm SAL  
Email: pharmacovigilance@algorithm-lb.com  
Phone: +961-9-222050 ext. 347  
Fax: +961-9-222604  
Website: www.algorithm-lb.com

This is a medicament  
- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.  
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.  
- The doctor and the pharmacist are experts in medicines, its benefits and risks.  
- Do not by yourself interrupt the period of treatment prescribed.  
- Do not repeat the same prescription without consulting your doctor.  
- Keep all medicaments out of reach of children.

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