1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

FEBRILEX+ 125 mg/1 mg/5 mg par 5 ml, syrup
Paracetamol, chlorphenamine, dextromethorphan

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

What is in this leaflet

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

1. What FEBRILEX+ is and what it is used for

FEBRILEX+ is a syrup for oral use combining different actions: paracetamol has an analgesic and antipyretic action; chlorphenamine has antihistaminic properties; dextromethorphan is a strong cough suppressant

It is indicated in :
- symptomatic treatment of non-productive cough and/or respiratory congestion associated with irritative or allergic conditions with cephalalgia and/or fever.
- acute rhinitis, allergic rhinitis, bronchial congestion, influenza coryza.

2. What you need to know before you take FEBRILEX+

Do not take FEBRILEX+ :
- If you are allergic to one of the active substances or any of the other ingredients of this medicine (listed in section 6).
- If you have narrow-angle glaucoma.
- If you have urinary retention risk associated with urethro-prostatic disorders.
- If you have respiratory insufficiency, asthmatic cough.
- If you are treated with MAOI (drugs prescribed for the treatment of some depressions).

- If you have phenylketonuria (hereditary disease detected at birth) due to the presence of aspartame.
- Children younger than 6 years old.

Warnings and precautions
Productive cough should be respected. All cough suppressant treatment will be preceded by a causal determination of the cough.
Because of presence of paracetamol: caution should be exercised in patients with impaired hepatic function (including Gilbert's syndrome), acute hepatitis, renal insufficiency, chronic alcoholism and weighing less than 50 kg.
Because of the presence of an antihistaminic (chlorphenamine): alcoholic beverages or use of sedatives (especially barbiturates) which increase the sedative action of antihistaminic should be avoided during the treatment. Because of the presence of a morphinic compound (dextromethorphan) caution should be exercised in case of liver disease.

Other medicines and FEBRILEX+
Interactions associated with paracetamol: laboratory test: paracetamol absorption can interfere with the assay method using phosphotungstic acid and blood sugar level dosage when using the glucose-oxydase-peroxydase method. Caution should be exercised if the medicine is taken concomitantly with colestyramine, barbiturates, primidone, isoniazid, rifampicin, alcohol, probenecid, zidovudine, anti-vitamin K anticoagulants, lamotrigine, metoclopramide and domperidone.
Interactions associated with chlorphenamine: increased activity of depressants of the central nervous system (hypnotics, anaesthetics). The increase of central atropinic effects should be taken into account in case of association with other anticholinergic substances (other antihistaminic, antidepressant, imipramin derivatives, neuroleptics, phenothiazine derivatives, antiparkisonians, anticholinergics, atropinic antispasmodics, disopyramide).
Interactions associated with dextromethorphan: do not associate with non-selective MAOI.
Tell your doctor or pharmacist if you are taking any other medicines.

Pregnancy and breast-feeding
FEBRILEX+ should not be administered to pregnant or potential child bearing women.
Administration to breastfeeding mothers is not recommended.

Driving and using machines
Because of antihistaminic presence, use with caution as drowsiness may be associated with the use of the drug.

FEBRILEX+ contains 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.
FEBRILEX+ contains sucrose sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), aspartame (E951) and propylene glycol (E1520).

3. How to take FEBRILEX+ ® Syrup

Children between 6 and 12 years old: 5 to10 ml syrup 3 to 4 times daily.
More than 12 years old and more than 50 kg: 15 ml syrup 3 to 4 times daily.
Do not exceed the dosage. The treatment duration should be as short as possible and should not exceed 5 days.
In adults below 50 kg of weight, the maximum daily dose of paracetamol should not exceed 60 mg/kg/day.
The daily dose of paracetamol should not exceed 2 g in the following situations: chronic alcoholism, liver failure, Gilbert's syndrome
In case of moderate to acute kidney failure, the dose of paracetamol should be adapted:

Glomerular filtration	Dose
10 – 50 ml/min	500 mg every 6 hours
< 10 ml/min	500 mg every 8 hours

If you take more FEBRILEX+ than you should
In case of overdose, an immediate transfer to hospital is recommended.

4. Possible side effects

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

Associated with paracetamol: rare: dizziness, malaise, overdose and intoxication, allergic reactions, abdominal pain, diarrhoea, nausea, vomiting, constipation, liver function disorders, liver failure, liver necrosis, icterus, pruritus, rash, sweating, angioedema, hives, headaches. Very rare: sterile pyuria (cloudy urines), thrombocytopenia, leucopoenia, pancytopenia, neutropenia, haemolytic anaemia, agranulocytosis, allergic reaction requiring treatment discontinuation, liver-toxicity, very rare cases of severe skin reactions have been reported, Undetermined frequency: nephropathy (interstitial, nephritis, tubular necrosis) following the extended use of high doses, hepatitis, anaemia, anaphylactic shock.

Associated with chlorphenamine: atropinic effects such as dry mouth, accommodation disorders, dysuria, mental disorder or excitation in elderly patients. These effects decrease after treatment discontinuation.

Associated with dextromethorphan: rarely constipation, somnolence, excitation, confusion, dizziness, nausea, vomiting, wheezing, skin allergic reaction.

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

5. How to store FEBRILEX+

Shelf-life: 3 years. Store below 30°C protected from light. 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 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 FEBRILEX+ contains
The active substances are paracetamol, dextromethorphan and chlorphenamine maleate.
Each 5 ml contains: 125 mg paracetamol, 5 mg dextromethorphan and 1 mg chlorphenamine maleate.
The other ingredients are: propylene glycol, (E1520) sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), aspartame (E951), citric acid, sucrose, xanthan gum, essence cherry, colour ponceau 4R (E124), purified water.

What FEBRILEX+ looks like and contents of the pack
Bottle of 150 ml.

Marketing Authorisation Holder and Manufacturer
Exphar s.a., Zoning Industriel de Nivelles Sud, zone II - Avenue Thomas Edison 105 - 1402 Thines – Belgium
Manufacturer
Gracure Pharmaceuticals Ltd., E-1105 Industrial Area, Phase-III, Bhiwadi (Raj) India.

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