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1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

FEBRILEX® Junior syrup 125 mg/1 ml per 5 ml, syrup Paracetamol, chlorphenamine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription however you should appropriately use it in order to get the best effects.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.
- You must contact a doctor if your symptoms worsen or do not improve after a few days.

In this package leaflet:

1. WHAT FEBRILEX JUNIOR IS AND WHAT IT IS USED FOR
2. BEFORE YOU USE FEBRILEX JUNIOR
3. HOW TO USE FEBRILEX JUNIOR
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE FEBRILEX JUNIOR
6. CONTENT OF THE PACK AND FURTHER INFORMATION

1. WHAT FEBRILEX JUNIOR IS AND WHAT IT IS USED FOR

This medicine is a combination of paracetamol (against fever and pain) and of chlorphenamine maleate (antiallergic).

It is indicated in children above 2 years in the symptomatic treatment of cold, rhinitis, influenza coryza together with:

- nasal discharge, flow of tears
- sneezing
- headache and /or fever

For children under 2 years of age, other medicines are available; ask your doctor or pharmacist.

2. BEFORE YOU USE FEBRILEX JUNIOR

Your child should not take FEBRILEX JUNIOR in the following cases:

- Hypersensitivity to any of the ingredients.
- Narrow-angle glaucoma.
- Urinary retention risk associated with urethro-prostatic disorders (chlorphenamine).
- Children under 2 years of age.

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Warnings and precautions

Talk to your doctor or pharmacist if you or your child:

- has severe liver disorders.
- suffers from kidney failure.
- takes other medicines. Read section "Taking other medicines"

This medicine contains paracetamol. Prolonged treatment should be avoided and treatment should be discontinued as soon as fever or pain disappears. Do not exceed the dosage.

If pain or fever persists or gets worse after a few days of treatment, talk to your doctor.

Talk to your doctor if any of the above mentioned warnings is or has been applicable to your child.

Other medicines and FEBRILEX Junior

If your child is taking or has recently taken other drugs, including drugs obtained without prescription, ask your doctor or pharmacist.

Ask your doctor or pharmacist if your child is treated with antiepileptic drugs.

If FEBRILEX Junior is used together with blood-thinning drugs, a blood monitoring may be required.

Refer to your doctor or pharmacist if your child uses barbiturates, carbamazepine, phenytoin, primidone, isoniazid, rifampicin, zidovudine, probenecid, lamotrigine, metoclopramide, domperidone or chloramphenicol.

Remark for diabetic patients: FEBRILEX Junior may affect the measure of glucose in the blood (glycaemia). Consult your doctor or nurse in charge of monitoring the diabetes of your child.

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. The increase of central atropinic effects should be taken into account in case of association with other anticholinergic substances.

Pregnancy and breastfeeding:

FEBRILEX Junior is not recommended if you are pregnant or breast-feeding.

In general, always ask your doctor or pharmacist before taking a medicine during pregnancy or while breastfeeding.

Driving vehicles and use of machines

Due to the presence of the antihistaminic compound, caution should be exercised when driving or operating machines because of the risk of dizziness.

FEBRILEX JUNIOR 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 Junior contains propylene glycol.

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If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

3. HOW TO TAKE FEBRILEX JUNIOR

Children between 2 and 6 years old: 5 ml syrup 3 to 4 times daily.
 Children between 6 and 12 years old: 10 ml syrup 3 to 4 times daily.
 More than 12 years old: 15 ml syrup 3 to 4 times daily.
 Do not exceed the dosage.

If your child has taken more FEBRILEX Junior than he should:

In case of overdose, contact immediately your doctor, pharmacist or the hospital even in case of suspicion of overdosage and even if any visible sign or symptom has not occurred yet as this will ensure that appropriate measures are rapidly taken. First signs of overdosage are vomiting, general malaise and abdominal pain. Liver toxicity is the main complication of overdosage.

4. POSSIBLE SIDE EFFECTS

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

Paracetamol:

Rare: dizziness, uneasiness, overdose and intoxication, allergic reactions, abdominal pain, diarrhoea, nausea, vomiting, constipation, troubled liver function, liver failure, liver necrosis, icterus, pruritus, rash, sweating, angioedema, hives, headaches.

Very rare: cloudy urine, thrombocytopenia, leukopenia, pancytopenia, neutropenia, haemolytic anaemia, agranulocytosis, severe allergic reactions have been reported.

Isolated cases: nephropathy (interstitial, nephritis, tubular, tubular necrosis) following the use of high doses of paracetamol, hepatitis, anaemia, anaphylactic shocks.

Chlorphenamine:

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

If you notice any side effects not mentioned in this package leaflet, or if some side effects become serious, please tell your doctor or pharmacist.

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.

5. HOW TO STORE FEBRILEX JUNIOR

Keep out of the sight and reach of children.

Do not use FEBRILEX Junior after the expiry date stated on the outer pack after the mention EXP.

Store at a temperature not exceeding 30 °C. Do not use FEBRILEX Junior syrup in case of visible signs of alteration.

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Medicines must not be disposed of down the drain or with the domestic waste. Ask your pharmacist what you should do with unused medicines. These measures are to protect the environment.

6. CONTENT OF THE PACK AND FURTHER INFORMATION

What FEBRILEX Junior contains

The active substances are paracetamol and chlorphenamine maleate.

5 ml syrup contains 125 mg paracetamol and 1 mg chlorphenamine maleate.

The other ingredients are: propylene glycol (E1520), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), aspartame (E951), citric acid, essence cherry, colour ponceau 4R (E124), sucrose, xanthan gum, purified water.

What FEBRILEX Junior looks like and contents of the pack

Bottle of 150 ml.

FEBRILEX ® Junior is a registered trademark of Exphar s.a.

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Manufacturer:

Gracure Pharmaceuticals Ltd., E-105

Industrial Area, Phase-III, Bhiwadi (Raj) India.

Last date of revision of this package leaflet: 01/2019