1.5.3 Patient Information Leaflet (PIL)

Package leaflet: Information for the patient

FEBRILEX 500 mg/5 mg/2 mg, tablets
Paracetamol/Phenylephrine hydrochloride/Chlorphenamine maleate

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 have 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 after 5 days

What is in this leaflet

1. WHAT FEBRILEX IS AND WHAT IT IS USED FOR

This medicine is a combination of paracetamol, phenylephrine hydrochloride and chlorphenamine maleate. It is used in adults from 15 years and from a bodyweight of 50 kg for symptomatic treatment of:
• influenza and feverish complaint (headaches, neuralgia, various pains, fever);
• nasal congestion or obstruction, cold, rhinorrhea, watery eyes, repeating sneezing;
• acute congestive nasopharyngitis complaint whether infectious or allergic: rhinitis, sinusitis, pharyngitis, tubar catarrh, nasopharyngitis infections.
In case of bacterial infection, a therapy by antibiotics should be recommended.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEBRILEX

Do not take FEBRILEX:

- If you are hypersensitivity to any of the ingredients
- In children under 15 years of age and under 50 kg
- In case of severe hypertension or uncontrolled treated hypertension
- In case of history of cerebrovascular accidents or risk factors for cerebrovascular accidents

- If you suffer from severe heart disease, coronary artery disease
- If you suffer from glaucoma (increased intraocular pressure) (chlorphenamine and phenylephrine)
- If you suffer from urinary retention associated with urethro-prostatic disorders (chlorphenamine and phenylephrine)
- In case of treatment within 2 weeks time with MAOIs, drugs used for the treatment of some depressions
- In case of use of vasoconstrictor drugs such as bromocriptin, pergolide, lisuride, cabergoline, ergotamine, dihydroergotamine or others drugs to decongest nose administered by oral or nasal route (phenylpropanolamine, phenylephrine, ephedrine,).
- In case of history of convulsions

This medicine MUST GENERALLY NOT BE USED, unless otherwise instructed by your doctor, during pregnancy and breastfeeding.
IN CASE OF DOUBT, IT IS ESSENTIAL TO ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST

Warnings and precautions:
Do not exceed the stated dose, do not prolong treatment more than 5 days and respect the above contra-indications.
Ask your doctor:

- in case of hypertension, heart disease, hyperthyroidism, confusion or diabetes;
- in case of concomitant use with drugs to treat migraine, especially drugs containing ergot alkaloid derivatives.
- if a surgery is planned and in case of use of halogenated anaesthetic agent it is recommended to discontinue the treatment a couple of days prior to the procedure because of risk of hypertension.
- in case of kidney failure, liver failure (including Gilbert's syndrome) and chronic alcoholism, the dose of paracetamol should be adapted.

The treatment should be discontinued in case of hypertension, tachycardia, palpitations and heart rhythm disorders, nausea or any neurological sign such as occurrence of headache or increased headache.

In case of purulent nasal secretion, of if fever lasts for more than 3 days or if symptoms last more than 5 days, CONSULT YOUR DOCTOR.

Athletes should be aware that this drug contains an active component (phenylephrine) which may induce a positive reaction to anti-doping tests.

Taking other medicines
Paracetamol absorption can distort the phosphotungstic acid and blood sugar level dosage when using the glucose-oxidase-peroxidase method. The drug should be used with care if

associated with colestyramine, barbiturates, primidone, isoniazide, rifampicine, alcohol, probenecide, zidovudine, vitamin K antagonist anticoagulants,
This drug contains the vasoconstrictor phenylephrine, and the antihistaminic chlorphenamine that should not be combined with alcohol or with other vasoconstrictor compounds such as bromocriptine, pergolide, lisuride, cabergolide, ergotamine, dihydroergotamine, methylergometrine, linezolid or with any other oral or nasal drug used to treat nasal congestion, or with any other antihistamic.

This drug should not be taken with other drugs containing ephedrine, phenylpropanolamine, pseudoephedrine or methylphenidate.
If you are taking or have recently taken another drug, including a drug obtained without prescription, ask your doctor or pharmacist.
If you have any doubt, do not hesitate to seek advice from your doctor or pharmacist.

Pregnancy and Breastfeeding:
FEBRILEX is not recommended to pregnant women and nursing mothers.
IN GENERAL, ALWAYS ASK YOUR DOCTOR OR PHARMACIST BEFORE TAKING A MEDICINE DURING PREGNANCY OR WHILE BREASTFEEDING.

Driving vehicles and use of machines
Because of antihistamine presence, use with caution when driving a car or operating machinery as drowsiness may be associated with the use of the drug.

3. HOW TO TAKE FEBRILEX
FEBRILEX should only be administered to adults (adolescent over 15 years and over 50 kg of bodyweight)
Adults: 1 tablet - 2 or 4 times a day with an interval of 4 hours between each intake.
Do not exceed recommended dosages and 5 days of treatment.

If you have taken more FEBRILEX tablets than you should:
An overdose of paracetamol may harm your liver.
In the event of overdose or accidental intoxication, inform your doctor immediately.

4. POSSIBLE SIDE EFFECTS
Like all medicines, FEBRILEX tablets may cause side effects, although not everybody gets them:
Phenylephrine hydrochloride:
Palpitation, hypertension, insomnia, nervousness, stimulation, anxiety, psychotic events, confusion, irritability, headache, anorexia, nausea or vomiting (phenylephrine)
Chlorphenamine maleate:

Dry mouth, vision disorders (accommodation), urinary disorders, somnolence, constipation, vertigo, wheezing, hypotension, excitability in elderly patients.
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, angioedeme, hypes, headaches.
Very rare: cloudy urines, thrombocytopenia, leucopoenia, pancytopenia, neutropenia, haemolytic anaemia, agranulocytosis, severe allergic reactions have been reported.
Isolated cases: nephropathy (interstitial, nephritis, tubular necrosis) following the use of high doses of paracetamol, hepatitis, anaemia, anaphylactic shocks.
Discontinue use if allergic reactions such as wheezing, rash or itching develop.

Rarely stroke (cerebrovascular accident) has been reported in patients treated with drugs containing phenylephrine especially when warning or contra-indications had not been followed.

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.

5. HOW TO STORE FEBRILEX

Keep out of the reach and sight of children.
Do not use FEBRILEX tablets after the expiry date stated on the outer pack.
Store at a temperature not exceeding 30°C.
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. CONTENT OF THE PACK AND FURTHER INFORMATION

What FEBRILEX contains?
The active substances are paracetamol (500 mg), phenylephrine hydrochloride (5mg) and chlorphenamine maleate (2 mg)
The other ingredients are: sodium starch glycolate, maize starch, microcrystalline cellulose, sodium benzoate (E211), sodium lauryl sulphate, polyvinyl pyrrolidone, tartrazine (E102), magnesium stearate, talc.

What FEBRILEX looks like and contents of the pack?
This medicine is presented in the form of round, yellow, scored tablets.
Paper pouch of 4 tablets in alu-alu strip.

FEBRILEX ® is a registered trademark of
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