FENAFEX TABLET®

Fexofenadine Hydrochloride (60mg)

What is in the leaflet

- 1. What Fenafex is used for
- 2. How Fenafex works
- 3. Before you use Fenafex
- 4. How to use Fenafex
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Fenafex
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

What Fenafex is used for

Fenafex is used in adults and children of 12 years old and older for the relief of symptoms associated with:

- Allergic inflammation of the nasal airways (allergic rhinitis) such as runny nose, sneezing, itchy nose/palate/throat and itching, watery, red eyes.
- Long term allergic skin reaction (chronic idiopathic urticaria).

How Fenafex works

It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction.

Before you use Fenafex

- When you must not use it
- Hypersensitive to fexofenadine or any of its ingredients.
- Before you start to use it

Tell your doctor if you:

- Have kidney or liver disease
- Are an elderly
- Use for children less than 6 years old
- Are a pregnant women
- Are breast-feeding

If you are not sure whether you should start taking this product, consult your doctor.

- Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription. You may need to use different amounts of these medicines, or you may need to take different medicines. Your doctor will advise you. In particular, tell your doctor if you take any of the following:

• Antacids containing aluminium and/or magnesium hydroxides (used to neutralizes stomach acidity)

- Erythromycin (antibiotic)
- Ketoconazole (for treating fungal infections)

- Pregnancy and lactation

Fexofenadine should only be used when, in the opinion of the doctor, the potential benefits justify the potential risks to the foetus and mothers.

Terfenadine was found to cross into human breast milk. As such, fexofenadine is not recommended for use during breast-feeding.

How to use Fenafex

Always take Fenafex exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How much to use

Adults and children (above 12 years of age) Allergic inflammation of the nasal airways: 2 tablets (120mg) once daily, either as a single dose or in two divided doses.

<u>Long-term allergic skin reactions:</u> 3 tablets (180mg) once daily.

Kidney impairment:

1 tablet (60mg) once daily

Elderly or individuals having liver problems: No dosage adjustment is required for these individuals.

- When to use it

Take your medicine at the same time every day.

- How long to use it

Continue to take your medicine as long as your doctor tells you.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest

hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause dizziness, drowsiness, and dry mouth.

While you are using it

- Things you must do
- Always take Fenafex exactly according to the instructions given to you by your doctor or pharmacists. Check with your doctor or pharmacist if you are unsure.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- If you become pregnant, or plan on becoming pregnant while taking Fenafex, tell your doctor immediately.
- If you are about to be started on a new medicine, remind your doctor and pharmacist that you are taking Fenafex.
- Things you must not do
- Do not use Fenafex after the expiry date which is stated on the carton and bottle/blister.
- Do not stop taking the medicine unless advised by your doctor.
- Do not give Fenafex to anyone else, even if they have the same symptoms or condition as you.
- Things to be careful of
- Driving and using machines:

Fenafex is not known to affect your driving ability or operation of machineries. However, it is advisable to check the individual response before driving or performing complicated tasks.

Side effects

Like many products, Fenafex may cause side effects in some people, particularly upon the first consumption but not everyone will exhibit the same symptoms.

Tell your doctor if you have any of these symptoms:

• Drowsiness, headache, dizziness, nausea and fatigue.

If you notice any side effects not listed in

this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public -> Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of Fenafex

Storage

Store in a cool, dry place below 30°C and protect from light.

Keep out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Fenafex comes in an orange oval biconvex film coated tablet embossed with "T20" on one side and a breakline on the other side.

- Ingredients

- Active ingredient

Each tablet contains 60mg of Fexofenadine hydrochloride.

- Inactive ingredients

Microcrystalline cellulose, starch, croscarmellose sodium, sodium lauryl sulfate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, hypromellose E5 & E15, methylene chloride, titanium dioxide, talc, PEG 6000, erythrosine lake & sunset yellow (colouring) and dimethicone.

- Packing

Fenafex tablet comes in amber plastic bottle of 60, 100 or 500 tablets and aluminium foil strip of 10, 30, 50, or 100 tablets.

- <u>MAL Number</u> MAL06091403AZ

Manufacturer

Sriprasit Pharma Co. Ltd., 619 Charoen Rath Road, Klongsarn, Bangkok, 10600 Thailand.

Product Registration Holder

IMEKS Pharma Sdn. Bhd. No. 5 & 9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

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