

TRITOFEN SYRUP

Consumer Medication Information Leaflet (RiMUP)

Ketotifen Fumarate (1mg/5ml)

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What TRITOFEN is used for

TRITOFEN is used for the prevention of asthma, allergic bronchitis (inflammation of the airways in the lungs) and asthmatic symptoms associated with hay fever. It is also used for the symptomatic treatment of multi system allergy, allergic rhinitis (inflammation of the lining inside the nose) and allergic skin reactions.

How TRITOFEN works

The active ingredient of this medicine is ketotifen. Ketotifen is a type of antihistamine that alleviates allergic problems by blocking the reactions due to the release of chemicals in the body when exposed to allergens.

Before you use TRITOFEN

- When you must not use it

Do not take TRITOFEN if you are allergic or hypersensitive to the ketotifen or other ingredients of this product.

Do not take TRITOFEN if you are taking Central nervous system depressants and medicines for high blood pressure.

Do not take TRITOFEN for abortive acute attacks of asthma.

- Before you start to use it

Tell your doctor if:

- You are taking oral antidiabetic medicines to control your diabetes
- You are allergic to any medicines, food and dyes.

- You are pregnant, trying to get pregnant, think you may be pregnant or breastfeeding.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription and herbal medicines.

Tell your doctor or pharmacist if you are taking:

- Central nervous system depressants (Medicines used to treat anxiety and sleep disorders).
- Antihypertensives (to lower blood pressure)
- Antidiabetic agents (medicines used to control the level of blood glucose) and antihistamine

How to use TRITOFEN

- How much to use

You should take TRITOFEN exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

Adults: 1 mg twice daily, increased to a maximum of 2 mg, twice daily if necessary.

Children older than 3 years: 1 mg, twice daily.

Children aged 6 months-3years: 0.5 mg twice a day.

- When to use it

TRITOFEN is to be used as directed by your doctor or pharmacist.

- How long to use it

Continue taking TRITOFEN for as long as your doctor recommends.

It should not be withdrawn suddenly when long term treatment is begun

If you forget to use it

If you forget to take TRITOFEN, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten 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.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking TRITOFEN.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Avoid alcohol consumption.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give TRITOFEN to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

During the first few days of treatment with ketotifen, your reactions may be impaired. Care must be taken while driving a vehicle or operating a machine.

If intercurrent infection occurs, ketotifen treatment must be supplemented by specific anti-infectious therapy.

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Side effects

Like all medicines, TRITOFEN can cause side effects, although not everybody gets them. You may experience drowsiness, impaired reaction, dizziness and / or dry mouth. You may also have weight gain.

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 TRITOFEN

- Storage

Stored in a cool place protected from light.

- Disposal

Do not use after the expiry date stated on the label.

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.

Product Description

- What it looks like

Cleared, red coloured pleasantly flavoured viscous liquid.

- Ingredients

- Active ingredient
Ketotifen Fumarate

- Inactive ingredients

Propylene glycol, E supra (Fast red), Glycerin, Sodium propyl hydroxybenzoate, Sorbitol (70% solution), Anhydrous Citric Acid, Sodium methyl hydroxybenzoate, Purified water, Soluble essence of pepper mint, American Ice cream soda.

- MAL number:

MAL19972098AZ

Manufacturer

FDC Limited
B-8, M.I.D.C Waluj
Dist. Aurangabad
431136

Product Registration Holder

Unimed sdn bhd
No.53 Jalan Tembaga SD 5/2B,
Bandar Sri Damansara,
52200 Kuala Lumpur

Date of revision

07/10/ 2017

Serial number:

NPRA(R4/1)190917/00251