

TEFODINE

contains the active ingredient fexofenadine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TEFODINE.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking TEFODINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What TEFODINE is used for

TEFODINE 120 and 180 are used to relieve the symptoms of hayfever (seasonal allergic rhinitis) such as sneezing, runny or itchy nose, and/or watery, red or itchy eyes.

TEFODINE 180 is also used to relieve the symptoms of urticaria, otherwise known as hives or itchy rash.

TEFODINE belongs to a class of medicines known as antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine.

Histamine is produced by the body in response to foreign substances that the body is allergic to.

Your doctor, however, may prescribe TEFODINE for another purpose. Ask your doctor if you have any questions about why TEFODINE has been prescribed for you.

There is no evidence that TEFODINE is addictive.

Before you take TEFODINE

When you must not take it

Do not take TEFODINE if:

- **you have an allergy to fexofenadine, terfenadine (Teldane®) or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include development or worsening of a skin rash, difficulty breathing or faintness.

Do not take TEFODINE if you are pregnant or breastfeeding, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not take TEFODINE after the expiry date (Exp) printed on the pack.

Do not take TEFODINE if the packaging is torn or shows signs of tampering.

Before you start to take it

You must tell your doctor or pharmacist:

- **if you are allergic to any other medicines, foods, dyes or preservatives.**

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Use in children

There is currently not enough information available to recommend TEFODINE for use in children under 12 years of age.

How to take TEFODINE

Take TEFODINE with a glass of water. It may be taken with or without food.

How much to take

For relief of the symptoms of hayfever, the usual dosage for adults and children over 12 years of age is one TEFODINE 120 tablet daily, or one TEFODINE 180 tablet daily.

For relief of the symptoms of urticaria, the usual dosage for adults and children over 12 years of age is one TEFODINE 180 tablet daily.

TEFODINE can be stopped when you obtain relief from your symptoms, and restarted if symptoms recur.

Do not take more than the recommended dose.

If TEFODINE does not relieve your symptoms, do not take extra tablets. Tell your doctor or pharmacist.

If you take too much TEFODINE (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TEFODINE.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are taking TEFODINE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking TEFODINE.

Tell your doctor or pharmacist if you become pregnant while you are taking TEFODINE.

Things you must not do

Do not give TEFODINE to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor or pharmacist says to.

Things to be careful of

Make sure you know how you react to TEFODINE before you drive a car or operate machinery. TEFODINE is unlikely to make you drowsy. If you are drowsy, do not drive a car or work with machinery.

Stop taking TEFODINE 48 hours before you have any skin tests.

Antihistamines may interfere with the results of skin tests.

Try to avoid contact with known substances you are allergic to.

Hives are sometimes caused by allergy to certain foods. You should talk to your doctor for more information or if you are worried about this.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking TEFODINE.

TEFODINE helps most people with allergies, but it may have unwanted effects in a few people.

Like other medicines, TEFODINE can cause some side effects. If the side effects listed below occur, they are most likely to be minor and temporary.

Although most people will not experience any, some of the side effects that may occur with TEFODINE are:

- headache
- tiredness
- nausea
- indigestion
- dizziness
- drowsiness.

Other unwanted effects not listed above may occur in some people taking TEFODINE. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using TEFODINE

Storage

Keep TEFODINE where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep TEFODINE tablets in their pack until time to take.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store TEFODINE or any other medicines in the bathroom or near a sink.

Do not leave TEFODINE in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor or pharmacist tells you to stop taking TEFODINE or the medicine has passed the expiry date, ask your pharmacist what to do with any unused or out of date medicine.

Product description

TEFODINE tablets can be bought without a doctor's prescription.

What it looks like

TEFODINE tablets come in two strengths:

- TEFODINE 120 - peach coloured, circular, biconvex film-coated tablets, embossed with 'F' on one side and plain on the other side
- TEFODINE 180 - peach coloured, capsule-shaped, biconvex film-coated tablets, embossed with 'F' on one side and plain on the other side.

TEFODINE is available in blister packs of 10, 20 and 30 tablets.

Ingredients

The active ingredient in TEFODINE is fexofenadine hydrochloride.

- each TEFODINE 120 contains 120 mg of fexofenadine hydrochloride
- each TEFODINE 180 contains 180 mg of fexofenadine hydrochloride.

The tablets also contain:

- microcrystalline cellulose
- lactose
- povidone
- croscarmellose sodium
- maize starch
- sodium lauryl sulfate
- purified talc
- magnesium stearate
- Opadry II brown 85G86605.

The tablets do not contain gluten, sucrose, tartrazine or any azo dyes.

Supplier

Arrow Pharmaceuticals
24 Rothschild Ave
Rosebery NSW 2018

Australian registration numbers:
TEFODINE 120 - AUST R 129141
TEFODINE 180 - AUST R 129142

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June 2006.