

XERGIC



Flexfenadine Hydrochloride 30 mg, 60 mg, 120mg & 180mg Tablets

What is in this leaflet

This leaflet answers some common questions about XERGIC. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have benefits and risks. 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 XERGIC is used for

XERGIC is used to relieve the symptoms of hayfever (seasonal allergic rhinitis) such as sneezing, itchy, watery or red eyes, and itchy, blocked or runny nose. XERGIC 60 mg tablets are also used to relieve the symptoms of perennial allergic rhinitis, a similar allergy that occurs all year round and is caused by things such as house dust, mites, mould and pets. The XERGIC 180 mg tablets are also used to relieve the symptoms of urticaria, otherwise known as hives or itchy rash.

XERGIC contains the active ingredient fexofenadine and belongs to a group of medicines called antihistamines. It works by blocking the action of histamine and other substances produced by the body, which are causing your allergies or itchiness.

XERGIC is a non-sedating antihistamine, which means it should not make you drowsy or slow down your reactions. However, a few people may be affected and care should be taken when you are driving or operating machinery.

XERGIC is not recommended for use in children under the age of 6, as its safety and effectiveness have not been established in this age group.

There is no evidence that XERGIC is addictive.

Before you take XERGIC

When you must not take it

Do not take XERGIC if you are allergic to any other medicines containing fexofenadine (such as TELFAST), terfenadine (such as TELDANE) or any of the other ingredients in XERGIC. These are listed at the end of this leaflet.

Do not take XERGIC if the expiry date (EXP.) printed on the pack has passed. If you take this medicine after the expiry date, it may not work as well.

Do not take XERGIC if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.
They will discuss the risks and benefits of taking XERGIC during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or wish to breastfeed.
They will discuss the risks and benefits of taking XERGIC when breastfeeding.

Taking other medicines

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

How well XERGIC works may be affected if you are taking antacids. Your doctor or pharmacist can tell you what to do if you are taking antacids.

How to take XERGIC

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How to take XERGIC

Swallow the tablets whole with a glass of water.

XERGIC may be taken with or without food.

Children aged 6 to 11 years:

For the relief of the symptoms of hayfever, the usual dosage is one XERGIC 30 mg tablet twice daily when required.

Adults and children 12 years and older:

For the relief of the symptoms of perennial allergic rhinitis, the usual dosage is one XERGIC 60 mg tablet twice daily when required.

For the relief of the symptoms of hayfever, the usual dosage is one XERGIC 60 mg tablet twice daily or one XERGIC 120 mg tablet daily, or one XERGIC 180 mg tablet daily when required.

For relief of the symptoms of urticaria, the usual dosage is one XERGIC 180 mg tablet daily when required.

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

If you take too much XERGIC (overdose)

Immediately contact your doctor, or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency department at the nearest hospital, if you think you or anyone else may have taken too much XERGIC. Do this even if there are no signs of discomfort or poisoning.

Side effects

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

All medicines can have side effects. Although most people will not experience any side effects, some of the side effects that may occur with XERGIC are:

- headache
- tiredness
- nausea
- dizziness
- drowsiness

These same effects were seen in patients taking dummy or placebo capsules during the clinical studies on the innovator product, Telfast™.

Other side effects not listed above may also occur in some patients.

After taking XERGIC

Storage

Keep XERGIC 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 your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

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

Do not store XERGIC or any other medicine in the bathroom or near a sink.

Do not leave XERGIC 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 XERGIC, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

XERGIC tablets are available in 4 strengths:

XERGIC 30 mg tablets are peach, circular, biconvex film-coated tablets. Plain on both sides.

XERGIC 60 mg tablets are yellow, circular, biconvex film-coated tablets. Plain on both sides.

XERGIC 120 mg tablets are peach, oblong, bi-convex film-coated tablets. Plain on both sides.

XERGIC 180 mg tablets are yellow, oblong, bi-convex film-coated tablets. Plain on one side with a central breakline on the other side.

Ingredients

The active ingredient in XERGIC is fexofenadine hydrochloride. Each XERGIC tablet contains either 30 mg, 60 mg, 120 mg or 180 mg of fexofenadine hydrochloride.

The tablets also contain the following inactive ingredients: croscarmellose sodium, maize starch, microcrystalline cellulose, magnesium stearate, hypromellose, povidone, titanium dioxide, macrogol 400, macrogol 4000, iron oxide yellow C177492, iron oxide red C177491 (30 mg and 120 mg tablets only).

The tablets do not contain sucrose or lactose and are gluten free.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd
PO Box 11183
Ellerslie
Auckland.

Freephone: 0800 168 169

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2 February 2009
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