

NEW ZEALAND CONSUMER MEDICINE INFORMATION

XERGIC

Fexofenadine hydrochloride film coated tablets

120 mg & 180 mg (New formulation)



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 risks and benefits.

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

Keep this leaflet with the 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.

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 which 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.

There is no evidence that this medicine is addictive.

This medicine is available from a pharmacy.

Before you take Xergic

When you must not take it

Do not take Xergic if you have an allergy to:

- any medicine containing fexofenadine or terfenadine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not breast feed if you are taking this medicine.

The active ingredient in Xergic may pass into breast milk and there is a possibility that your baby may be affected.

Do not give Xergic 120 mg or Xergic 180 mg to children under 12 years old.

Safety and effectiveness in children younger than 12 years has not been established.

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

Before you start to take it

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

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- liver disease
- kidney disease
- heart disease.

There is limited information about using Xergic in elderly people, and people with liver, kidney or heart disease. Talk to your doctor or pharmacist if you have any questions.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant.

There is limited information about this medicine being used in pregnancy. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell him or her before you start taking Xergic.

Taking other medicines

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

Some medicines and Xergic may interfere with each other.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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 box, ask your doctor or pharmacist for help.

How much to take

Adults and children aged 12 years or older:

Seasonal Allergic Rhinitis (Hayfever)

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

Urticaria (Hives or Itchy Rash)

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

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

Ask your pharmacist to give you some information on self-help tips to help reduce allergy and hayfever symptoms.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

When you need to take the medicine, take it at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine with or without food.

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of Xergic.

How long to take it

Take this medicine when required for your allergies or urticaria. This medicine helps to relieve your symptoms. Talk to your doctor or pharmacist about how long you should continue taking this medicine for.

For hives or itchy rash, stop using this medicine when the rash and itching have gone.

If you forget to take it

If it is nearly time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Xergic. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include dizziness, drowsiness and dry mouth.

While you are taking Xergic

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Xergic.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any skin tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some skin tests.

Things you must not do

Do not take Xergic to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Xergic affects you.

This medicine is unlikely to affect your ability to drive or operate machinery but it may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

This medicine helps most people with hayfever, allergies or urticaria, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- drowsiness
- nausea
- fatigue
- dizziness

The above list includes the more common side effects of your medicine. These same effects were seen in patients taking dummy or placebo tablets during clinical studies.

Tell your doctor as soon as possible if you notice any of the following:

- sleeping problems
- disturbing dreams
- nervousness
- rash

The above list includes side effects that may require medical attention. These side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using Xergic

Storage

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

If you take the tablets out of the pack they may 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 it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Xergic 120 mg tablets:

Pink coloured, oval shaped, biconvex film coated tablets, debossed with "FXF" on one side and "120" on the other side. Each tablet contains fexofenadine hydrochloride 120 mg.

Xergic 180 mg tablets:

Pink coloured, oval shaped, biconvex film coated tablets, debossed with "FXF" on one side and "180" on the other side. Each tablet contains fexofenadine hydrochloride 180 mg.

Ingredients

Xergic contains fexofenadine hydrochloride as the active ingredient.

It also contains:

- cellulose
- mannitol
- maize starch
- croscarmellose sodium
- colloidal silicon dioxide
- magnesium stearate
- Opadry Pink (contains hypromellose, titanium dioxide, macrogol, allura red AC lake and iron oxide black).

This medicine does not contain lactose, sucrose or gluten.

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 168 169

Date of Information

31 August 2016
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