

XOLAIR(R)

Omalizumab(rch)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Xolair.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

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

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

Keep this leaflet.

You may need to read it again.

What Xolair is used for

Xolair is used to prevent or relieve the symptoms of allergic asthma in people who are already using preventer puffers containing steroids. Asthma is a disease where the lining

of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to a reaction to house dust mites, smoke or other irritants.

Xolair contains omalizumab, a monoclonal antibody produced by recombinant DNA technology. It works by blocking a substance produced by the body called immunoglobulin E (or IgE). IgE is involved in causing symptoms of asthma. Your doctor will measure the amount of IgE in your blood before starting your treatment with Xolair.

This medicine can be used in adults and in children aged 12 years or over.

Elderly patients are given the same dosage as younger adults.

Ask your doctor if you have any questions about why Xolair has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

Xolair is only available with a doctor's prescription. It is not addictive.

Before you have Xolair

When you must not have it

Do not have Xolair if you have an allergy to:

- * omalizumab (the active ingredient in Xolair) or any of the other 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.

Before you have it

Tell your doctor if you get severe allergic reactions (called anaphylaxis) to any medicines, foods, dyes, preservatives, bee stings, insect bites, etc.

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

- * hyper-IgE syndrome, a condition where you have high levels of IgE in your blood
- * an allergic skin condition
- * a lung problem caused by a fungus called Aspergillus
- * an infection caused by a parasite
- * a low platelet count (thrombocytopenia)

There is no information on the use of Xolair in people who have any of the above conditions. If you are not sure whether any of these conditions apply to you, your doctor can advise you.

Tell your doctor if you have diabetes mellitus, or any intolerance of dietary sugars.

Xolair contains sucrose.

Tell your doctor if you are pregnant or intend to become pregnant or wish to breast-feed your baby.

There is not much information on the use of Xolair during pregnancy or breast-feeding. If it is necessary for you to have this medicine, your doctor will discuss with you the

benefits and risks involved.

If you have not told your doctor about any of these things, tell him/her before you have Xolair.

Taking other medicines

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

Xolair has been used together with other common medicines for asthma. It is possible that some medicines and Xolair could interfere with each other. Your doctor or pharmacist can advise you.

How Xolair is given

This medicine is given as a subcutaneous injection. That means that it is injected into the fat layer just under the skin. Your doctor or nurse will give the injections. The injections are usually given in the upper arm or thigh.

How much is given

Your doctor will work out how much Xolair you need and how often you will be given the injections. This will depend on your body weight and the amount of IgE measured in your blood before the start of treatment.

The recommended dose of Xolair ranges from 150 to 750 mg of Xolair every four weeks. Doses of more than 300 mg are given fortnightly. You will need to continue your current asthma medicines when you start Xolair treatment but after 16 weeks, if your symptoms are well controlled, your doctor may be able to reduce or stop other asthma medicines that you are taking. Your doctor will discuss this with you.

If you are given too much (Overdose)

If you think that you may have been given too much Xolair, immediately tell your doctor or nurse.

No cases of overdose with this medicine have been reported.

While you are having Xolair

Things you must do

If you become pregnant while having treatment with Xolair, tell your doctor.

Keep all of your doctor's appointments so that you don't miss any injections and your progress can be checked.

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

Tell any other doctor, dentist or pharmacist who treats you that you are having Xolair.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Xolair affects you.

Side effects

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

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Tell your doctor if you notice any of the following side effects and they worry you:

- * bruising, redness or pain at the injection site
- * mild skin rash
- * headache
- * tiredness
- * hair loss
- * joint pain
- * joint swelling
- * muscle pain

Tell your doctor immediately if you notice any of the following signs:

- * weakness or paralysis of limbs or face, loss of sensation, difficulty speaking or understanding, transient loss of vision in one eye
- * abnormal bleeding or bruising
- * pain, numbness or tingling in the arms and legs, lumps or raised patches in the skin, weakness and fatigue, loss of appetite, and weight loss

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any signs of an allergic reaction to Xolair.

Symptoms of an allergic reaction may include:

- * severe rash, itching or hives on the skin
- * swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing, or swelling of any other parts of the body
- * fast heart beat, dizziness and light headedness
- * wheezing or shortness of breath

If an allergic reaction to Xolair occurs it usually happens within 2 hours after the Xolair injection. However, some allergic reactions have been reported beyond 2 hours and even beyond 24 hours after a Xolair injection.

A specific type of allergic reaction

(serum sickness) has also been observed in patients treated with Xolair or similar products. Signs include joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes and occur typically within one to five days after the injection.

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

Other side effects not listed above may happen in some people.

After using Xolair

Storage

It is unlikely that you will have to store Xolair at home.

If you do have to store it:

- * Keep the vials in the original container until it is time to take them to the doctor.
- * Keep them in the refrigerator. Do not freeze them.
- * Do not store Xolair or any other medicine in the bathroom or near a sink.
- * Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines. Xolair will keep well if it is kept cool and dry.

Keep the medicine where children cannot reach it.

Disposal

If your doctor stops your treatment with Xolair or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.

Product description

What it looks like

Each pack of Xolair contains a 150 mg vial of sterile powder and one ampoule of sterile water for injections for use in dissolving the powder.

Ingredients

Each vial of Xolair contains the active ingredient, omalizumab. It also contains:

- * sucrose
- * histidine
- * histidine hydrochloride monohydrate
- * polysorbate 20

Sponsor

Xolair is supplied in Australia by:

NOVARTIS Pharmaceuticals
Australia Pty Limited

ABN 18 004 244 160

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North Ryde NSW 2113

Telephone 1-800-671-203

(R) = Registered Trademark

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