

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**Allergic asthma**

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 6 years or over in allergic asthma.

Chronic Spontaneous Urticaria (CSU)

Xolair is used to treat Chronic Spontaneous Urticaria in adults and adolescents (12 years of age and older) whose CSU symptoms are not well controlled by antihistamines.

Xolair works by blocking a substance called immunoglobulin E (also known as IgE) which is produced by your body. As a consequence the activity of specific receptors and/or cells in your body which play a key role in causing chronic spontaneous urticaria are reduced. This leads to a reduction of your symptoms, like itching and hives.

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, latex 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 kidney or liver problems.

Talk to your doctor about using Xolair if you have kidney or liver problems.

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.

Tell your doctor, if you ever had an allergic reaction to latex (information specific to the needle cap of the pre-filled syringe).

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, as well as H1 or H2 antihistamines and LTRAs for chronic spontaneous urticaria. 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**Allergic asthma**

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 75 to 750 mg of Xolair every four weeks. Some doses are split into two injections given fortnightly, depending on your body weight and IgE levels. 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.

Chronic spontaneous urticaria

You will be given 1 or 2 injections of 150 mg at a time every four weeks.

Continue taking your current medicine for CSU during Xolair treatment. Do not stop taking any medicine without talking to your doctor first.

However, if you are being treated for CSU, your doctor may stop Xolair treatment from time to time so that your symptoms can be assessed. Follow your doctor's instructions.

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 swelling
- fever (very common in children)
- sore throat and blocked nose (nasopharyngitis)
- feeling of pressure or pain in the cheeks and forehead (sinusitis and sinus headache)

- upper respiratory tract infection, such as inflammation of the pharynx and common cold
- burning sensation or pain when passing urine and having to urinate frequently (possible symptom of a urinary tract infection)
- pain in upper or lower limbs (arms and/or legs)
- pain in muscles and/or bones and/or joints (musculoskeletal pain, myalgia, arthralgia).

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

- 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 heartbeat, dizziness and light-headedness
- wheezing or shortness of breath.

If you have a history of severe allergic reactions (anaphylaxis) unrelated to Xolair you may be more at risk of developing a severe allergic reaction following Xolair administration.

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.

Churg-Strauss and Hypereosinophilic syndrome have been observed in patients treated with Xolair. The symptoms may include one or more of the following: swelling, pain or rash around blood or lymph vessels, high level of a specific type of white blood cells, worsening problems with breathing, nasal congestion, heart problems, pain, numbness, tingling in the arm and legs.

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 pre-filled syringes 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.
- Do not use Xolair beyond the expiry date on the label.

- Do not use the product if there are signs of deterioration.
- Do not use Xolair if the pack is damaged or shows signs of tampering.

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

Solution for injection in pre-filled syringe:

Each pack of Xolair contains 1 pre-filled syringe. One syringe of 0.5 ml solution contains 75 mg omalizumab. One syringe of 1 ml solution contains 150 mg omalizumab.

Ingredients

Powder and solvent for solution for injection:

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.

Solution for injection in pre-filled syringe:

Each pre-filled syringe of Xolair contains the active ingredient, omalizumab. It also contains:

Solution for injection in pre-filled syringe:

- L-arginine hydrochloride
- L-histidine
- L-histidine hydrochloride monohydrate
- polysorbate 20
- water for injections.

Sponsor

Xolair is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty

Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

® = Registered Trademark.

This leaflet was prepared in January 2016.

Australian Registration Numbers

Xolair 150 mg vial AUST R 82744

Xolair 75 mg solution for injection in pre-filled syringe AUST R 201124

Xolair 150 mg solution for injection in pre-filled syringe AUST R 201126

(xol280116c.doc) based on PI (xol280116i.doc)