

PART III: CONSUMER INFORMATION

XOLAIR®
(omalizumab)

This leaflet is part III of a three-part "Product Monograph" published when XOLAIR® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XOLAIR®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

Read all of this leaflet carefully before you are given this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse or pharmacist.

What the medication is used for:Asthma

XOLAIR® (omalizumab) is a prescription medicine that has been shown to significantly decrease the incidence of asthma exacerbations and improve control of asthma symptoms in people who:

- Are 12 years of age and above
- Have moderate to severe persistent asthma. This means they have 1 or more of the following:
 - Asthma symptoms every day
 - Daily need for a rescue inhaler
 - 2 or more asthma attacks a week
 - 1 or more nights a week waking up with asthma symptoms
 - below-normal reading (less than 80%) from a tool called a peak flow meter, which measures how well the lungs work
- Have asthma that is triggered by year-round allergens in the air, which is confirmed by a doctor using a simple skin or blood test. This is known as allergic asthma
- Continue to have asthma symptoms even though they are taking inhaled steroids

Chronic Idiopathic Urticaria (CIU)

XOLAIR® (omalizumab) is a prescription medicine to treat Chronic Idiopathic Urticaria (CIU) in adults and adolescents (12 years of age and older) whose symptoms are not well controlled with antihistamines. XOLAIR® provides relief of CIU symptoms such as skin itch and hives.

What it does:What is allergic asthma?

Allergic asthma is how doctors describe a particular type of asthma. In people with this common condition, certain types of allergens can trigger asthma attacks and symptoms, such as coughing, wheezing, and shortness of breath.

You probably know about many of the things that can trigger your asthma. Cat or dog dander, dust mites, and cockroaches

are common examples of year-round allergens. What you may not know is how something as simple as visiting a friend who has a pet can lead to an asthma attack. The reason allergens can trigger asthma attacks is due, in part, to a body chemical called IgE.

What is Chronic Idiopathic Urticaria (CIU)

Chronic Idiopathic Urticaria (CIU) is a skin disease whose symptoms include itching and hives for at least 6 weeks. Persistent symptoms may be daily or episodic. Some people with CIU may also have swelling of the skin.

What is IgE?

IgE is short for immunoglobulin E. This substance, which occurs naturally in your body in small amounts, plays an important role in allergic asthma and CIU.

If you have allergic asthma, your body makes more IgE when you breathe in an allergen that triggers your asthma. This can cause a series of chemical reactions known as the "allergic-inflammatory process in allergic asthma". It can result in 2 things:

- The muscles that surround your airways begin to tighten. This is known as *constriction of the airways*
- Your airways become irritated and swell up. This is known as *inflammation of the airways*

Together, constriction and inflammation of the airways make it harder for you to breathe. This can lead to an asthma attack, also known as exacerbation.

What is XOLAIR®?

XOLAIR® is supplied as a powder in a small glass vial. The powder is dissolved in sterile water for injection before it is injected. Each vial delivers 150 mg of omalizumab. XOLAIR® is also available as a ready to use solution in a pre-filled syringe. The syringe is available in both 75 mg and 150 mg of omalizumab.

Asthma

XOLAIR® blocks a substance called immunoglobulin E (also known simply as IgE) which is produced by your body. IgE plays a significant role in causing asthma. Your doctor will measure the amount of IgE with a blood test and determine your body weight before starting the treatment with XOLAIR®. By blocking IgE, XOLAIR® helps stop the allergic-inflammatory process in allergic asthma.

Adding XOLAIR® injections to treatment with inhaled steroids has been clinically proven to help reduce the number of asthma attacks. XOLAIR® has not been proven to work in other allergic conditions.

XOLAIR® is not a rescue medicine and should not be used to treat sudden asthma attacks. It is not a substitute for the medicines you are already taking.

Chronic Idiopathic Urticaria (CIU)

XOLAIR® blocks a substance called immunoglobulin E (also

known simply as IgE) which is produced by your body. By binding to IgE, XOLAIR® reduces the activation of certain cells in your body and the release of histamine and other chemicals. This helps reduce symptoms of CIU, including itching and hives.

When it should not be used:

You should not be given XOLAIR®:

If you are hypersensitive (allergic) to omalizumab or any of the other ingredients of XOLAIR® (see below), or if you have ever had an allergic reaction to a XOLAIR® injection.

If you ever had an allergic reaction to latex (information specific to the needle cap of the pre-filled syringe).

Use in children

Experience with XOLAIR® in children under 12 years of age is insufficient for any recommendations regarding its use to be made.

Pregnancy

Ask your doctor, nurse or pharmacist for advice before taking any medicine.

Before starting treatment with XOLAIR®, tell your doctor if you are pregnant or think that you may be pregnant. Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy. Tell your doctor straight away if you become pregnant while being treated with XOLAIR®.

Breast-feeding

Ask your doctor, nurse or pharmacist for advice before being given any medicine.

Tell your doctor if you are breast-feeding. It is not known whether omalizumab, the active substance of XOLAIR®, passes into breast milk or in what ways this could affect the baby. Your doctor will discuss with you the benefits and potential risks of being given this medicine while you are breast-feeding.

Fertility

There are no human fertility data for XOLAIR®.

Driving and using machines

You may experience dizziness, sleepiness or fatigue after receiving XOLAIR®, in which case you should not drive or use machines.

What the medicinal ingredient is:

omalizumab

What the nonmedicinal ingredients are:

XOLAIR®75 mg and 150 mg solution for injection in pre-filled syringe: L-arginine hydrochloride, L-histidine hydrochloride, L histidine, polysorbate 20, water for injection (for the needle cap of XOLAIR® pre-filled syringe, see sections 2 and 7 for further information on latex).

XOLAIR®150 mg powder and solvent for solution for injection: histidine, histidine hydrochloride monohydrate,

polysorbate 20 and sucrose

What dosage forms it comes in:

XOLAIR®75 mg and 150 mg solution for injection in pre-filled syringe and sterile powder for reconstitution, 150 mg vial (125 mg/mL after reconstitution)

WARNINGS AND PRECAUTIONS

1- A severe allergic reaction called anaphylaxis can happen in some patients after receiving XOLAIR®. Anaphylaxis is a life-threatening condition. Signs and symptoms of anaphylaxis include difficulty breathing, light-headedness, rash, itching, and swelling of the tongue and throat (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

Anaphylaxis from XOLAIR® can happen as early as after the first injection or hours later, and/or after any XOLAIR® injection. Your doctor, or nurse should watch you for some time for signs and symptoms of anaphylaxis after injecting XOLAIR®. If you have any of the signs or symptoms of anaphylaxis, tell your doctor or nurse immediately, and get emergency medical treatment right away.

Your doctor or nurse should instruct you about starting emergency medical treatment and getting further medical care if you have any signs or symptoms of anaphylaxis.

2- Weakness or paralysis of limbs or face, loss of sensation, difficulty speaking or understanding, transient loss of vision in one eye could be symptoms of a transient ischemic attack or stroke. Seek immediate medical attention if you experience any such symptoms.

BEFORE you use XOLAIR®, talk to your doctor or pharmacist if you have:

- Hypersensitivity reaction to any drug (Warnings and Precautions)
- Any other known hypersensitivity (Warnings and Precautions)
- Any allergies to this drug or its ingredients or components of the container (Contraindications)
- If you ever had an allergic reaction to latex (information specific to the needle cap of the pre-filled syringe).

Parasite infections

If you are living in a region where parasite infections are frequent or traveling to such a region, please tell your doctor. XOLAIR® may weaken your resistance to such infections. If you are taking a treatment against parasite infection, please tell your doctor. XOLAIR® may reduce the efficacy of your treatment.

INTERACTIONS WITH THIS MEDICATION

Please inform your doctor or nurse if you are taking or have recently taken any other medicines, even those not prescribed. Never suddenly stop taking, or change the dose of, your

inhaled steroids or any other asthma medicine or of current medicine for CIU you are taking unless your doctor tells you to do so.

XOLAIR® can be used together with other medicines for asthma, as well as with H1 or H2 antihistamines and leukotriene receptor antagonists (LTRAs) for CIU, but it is still important to tell your doctor that you are taking them before you are given XOLAIR®.

PROPER USE OF THIS MEDICATION

Your doctor or nurse will give you XOLAIR® as an injection just under the skin.

A patient support program has been established to provide you with injection services. Contact your doctor to enroll.

Asthma

Based on your dose, your doctor will also tell you if you will need 1, 2, or 3 injections per dose. If you need more than 1 injection per dose, each will be given in a different area of your body.

You will receive 150 or 300 mg every four weeks, or 225, 300 or 375 mg every two weeks. You will probably need to continue taking your current asthma medicine during XOLAIR® treatment but after 16 weeks you may be able to reduce or stop any other asthma medication that you are taking. Your doctor will discuss this with you. You should not reduce the dose of other asthma medication without first discussing with your doctor, even if you are feeling better.

Chronic Idiopathic Urticaria (CIU)

XOLAIR® 150 mg or 300 mg are administered subcutaneously every 4 weeks. The efficacy of XOLAIR® in CIU patients depends on the quantity that is injected.

Usual dose:

Asthma

XOLAIR® is given once every 2 or 4 weeks. Your dose will be determined by your body weight and your IgE level, which your doctor will measure with a simple blood test. Based on your dose, your doctor will also tell you if you will need 1, 2, or 3 injections per dose. If you need more than 1 injection, each will be given in a different place on your body.

Because it is a controller or *maintenance medicine*, you will receive XOLAIR® on a regular schedule. It is important that you continue to receive your XOLAIR® injections even when you are feeling well.

Chronic Idiopathic Urticaria (CIU)

You will be given 1 or 2 injections at a time every 4 weeks.

Continue taking your current medicine for CIU during XOLAIR® treatment. Do not stop taking any medicine without talking to your doctor first.

Continue to use XOLAIR® for as long as your doctor tells you to do so.

If you have questions about how long to receive XOLAIR®, talk to your doctor or your pharmacist.

Overdose:

The maximum tolerated dose of XOLAIR® has not been determined. Single intravenous doses up to 4000 mg have been administered to patients without evidence of dose-limiting toxicities. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

If you think you have taken too much XOLAIR®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients treated with XOLAIR® can experience side effects.

The side effects caused by XOLAIR® are usually mild. In clinical studies, they were about as common in people who were given XOLAIR® as those who were given a placebo (or dummy) injection that did not contain omalizumab.

Some patients had a serious allergic reaction called anaphylaxis, occurring at an average of 2 out of 1000 patients (0.2%) or more. Should it happen, anaphylaxis quickly causes symptoms such as rash, itching, and swelling of the tongue and throat, which can make it hard to breathe and can be life threatening. If you think you are having an anaphylactic reaction, get medical attention right away. Please speak with your doctor about this information.

Take special care if you have a disorder where your own immune system attacks part of your own body (autoimmune disease).

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. If you have such a reaction after taking XOLAIR®, contact a doctor immediately.

In initial clinical studies in asthma, the number of observed malignancies was uncommon (<1%) in all studied patients who received XOLAIR® or a placebo injection containing no medication, with 0.5% reported in patients receiving XOLAIR® and 0.2% in patients receiving placebo injections. Results from a review of all the clinical trials now completed (double in size from the initial studies) and also results from a 5 year observational study found that XOLAIR® was not associated with an increased risk of malignancy. Please discuss this information with your doctor.

The most common side effects reported in patients who received XOLAIR® in clinical studies in asthma and CIU are listed below. This is not a complete list of all side effects reported with XOLAIR®.

- Injection-site reaction (bruising, redness, warmth, burning, stinging, or other discomfort around the injection site)
- Viral infections
- Upper respiratory tract infection
- Sinusitis
- Headache
- Sore throat
- Urinary tract infection

These side effects were about as common in patients receiving placebo.

Other less commonly observed side effects included pain, broken bones, leg pain, dizziness, joint pain, muscle pain, joint swelling, and hair loss.

If you notice hives, skin rash, injection site reactions or any side effects not mentioned in this leaflet, please inform your doctor or nurse.

If you experience any of these, tell your doctor straight away.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	numbness or tingling in the arms and legs, lumps or raised patches in the skin, weakness and fatigue, loss of appetite and weight loss (signs of so-called “Churg-Strauss syndrome”)			
	Joint appearance of some of the following symptoms: Joint pain, stiffness, rash, fever, swollen/enlarged lymph nodes (signs of so-called serum-sickness). When it occurs this is usually between one to five days after injection			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Rare Sudden severe allergic reaction (sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, fast heartbeat, dizziness and light headedness, shortness of breath, wheezing or trouble breathing)			√
Low blood platelet count with symptoms such as bleeding or bruising more easily than normal			√
Joint appearance of some of the following symptoms: Pain,			√

HOW TO STORE IT

XOLAIR® is to be stored in a refrigerator (2°-8°C). Do not freeze. In order to protect from light, store in the original package. Any unused product or waste material should be disposed of in accordance with local requirements. Your doctor or nurse will know this. Keep this medicine out of the sight and reach of children. Do not shake.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program Health Canada,
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.Novartis.ca>
or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at:
1-800-363-8883
or by contacting the patient support program at 1-866-996-5247

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