

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Xolair 75 mg solution for injection** **Xolair 150 mg solution for injection** Omalizumab

#### **Read all of this leaflet carefully before you start using Xolair.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Xolair is and what it is used for
2. Before you are given Xolair
3. How Xolair is given
4. Possible side effects
5. How to store Xolair
6. Further information

### **1. WHAT XOLAIR IS AND WHAT IT IS USED FOR**

The active substance of Xolair is omalizumab. Omalizumab is a man-made protein that is similar to natural proteins produced by the body; it belongs to a class of medicines called monoclonal antibodies. It is used to prevent asthma from getting worse by controlling symptoms of severe allergic asthma in adults and children (6 years of age and older) who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high-dose steroid inhalers or beta-agonist inhalers.

Xolair works by blocking a substance called immunoglobulin E (IgE), which is produced by the body. IgE plays a key role in causing allergic asthma.

### **2. BEFORE YOU ARE GIVEN XOLAIR**

#### **You should not be given Xolair**

- if you are allergic (hypersensitive) to omalizumab or any of the other ingredients of Xolair. The ingredients are listed in section 6 of this leaflet.

If you think you may be allergic to any of the ingredients, tell your doctor since you should not be given Xolair.

#### **Take special care with Xolair**

Xolair contains a protein, and proteins can cause serious allergic reactions in some people. Signs include rash, difficulty in breathing, swelling or feeling faint. If you have an allergic reaction after taking Xolair, contact a doctor as soon as you can.

A certain type of allergic reaction called serum sickness has been observed in patients treated with Xolair. The symptoms of serum sickness can be one or more of the following symptoms: joint pain with or without swelling or stiffness, rash, fever, swollen lymph nodes, muscle pain. If you experience any of these symptoms, or in particular if you experience a combination of such symptoms, contact your doctor immediately.

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 (marked eosinophilia), worsening problems with breathing, nasal congestion, heart problems, pain, numbness, tingling in the arm and legs. If you experience any of these symptoms, or in particular if you experience a combination of such symptoms, contact your doctor immediately.

Tell your doctor before you are given Xolair:

- If you have kidney or liver problems.
- If you have a disorder where your own immune system attacks parts of your own body (autoimmune disease).
- If you live in a region where infections caused by parasites are common or if you are travelling to such a region as Xolair may weaken your resistance to such infections.

Xolair does not treat acute asthma symptoms, such as a sudden asthma attack. Therefore Xolair should not be used to treat such symptoms.

Xolair is not meant to prevent or treat other allergy-type conditions, such as sudden allergic reactions, hyperimmunoglobulin E syndrome (an inherited immune disorder), aspergillosis (a fungus-related lung disease), food allergy, eczema or hay fever.

### **Children (under 6 years of age)**

Xolair should not be given to children under 6 years of age. There are not enough data in this age group.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription.

This is especially important if you are taking:

- medicines to treat an infection caused by a parasite, as Xolair may reduce the effect of your medicines,
- inhaled corticosteroids and other medicines for allergic asthma.

### **Pregnancy and breast-feeding**

You should not take Xolair when you are pregnant, unless this is considered necessary by your doctor.

If you plan to become pregnant, tell your doctor before starting treatment with Xolair. Your doctor will discuss with you the benefits and potential risks of being given this medicine during pregnancy.

If you become pregnant while being treated with Xolair, tell your doctor immediately.

You should not take Xolair when you are breast-feeding.

### **Driving and using machines**

It is unlikely that Xolair will affect your ability to drive and use machines.

## **3. HOW XOLAIR IS GIVEN**

Instructions on how to use Xolair are given in the section “Information for the healthcare professional”.

Xolair is given to you by a doctor or nurse as an injection just under the skin (subcutaneously).

Your doctor will work out how much Xolair you need, and how often you will be given it. This depends on your body weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in your blood.

Follow carefully all instructions given by your doctor or nurse.

### **How much you will be given**

You will be given 1 to 4 injections at a time, either every two weeks, or every four weeks.

Carry on taking your current asthma medicine during Xolair treatment. Do not stop taking any asthma medicines without talking to your doctor.

You may not see an immediate improvement in your asthma after beginning Xolair therapy. It usually takes between 12 and 16 weeks to have the full effect.

### **Use in children**

Xolair can be given to children and adolescents aged 6 years or older, who are already receiving asthma medicine, but whose asthma symptoms are not well controlled by medicines such as high dose steroid inhalers or beta-agonist inhalers. Your doctor will work out how much Xolair your child needs and how often it needs to be given. This will depend on your child's weight and the results of a blood test carried out before the start of the treatment to measure the amount of IgE in his/her blood.

### **If a dose of Xolair is missed**

Contact your doctor or hospital as soon as possible to re-schedule your appointment.

### **If you stop treatment with Xolair**

Do not stop taking Xolair unless your doctor tells you to. Interrupting or stopping the treatment with Xolair may cause your asthma symptoms to come back.

If you have any further questions on the use of this medicine, ask your doctor.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Xolair can cause side effects, although not everybody gets them. The side effects caused by Xolair are usually mild to moderate but can occasionally be serious:

The frequency of possible side effects listed below is defined using the following convention:

Very common	affects more than 1 user in 10
Common	affects 1 to 10 users in 100
Uncommon	affects 1 to 10 users in 1,000
Rare	affects 1 to 10 users in 10,000
Very rare	affects less than 1 user in 10,000
Not known	frequency cannot be estimated from the available data.

### Serious side effects include:

#### Rare side effects

- Sudden severe allergic reactions: if you notice any serious sudden signs of allergy or combination of signs such as rash, itching or hives on the skin, swelling of the face, lips, tongue, larynx (voice box), windpipe or other parts of the body, fast heart beat, dizziness and light-headedness, shortness of breath, wheezing or trouble breathing, or any other new symptoms, tell your doctor or nurse immediately.

#### Not known

- Development of one or more of the following symptoms: swelling, pain or rash around blood or lymph vessels, high level of a specific type of white blood cells (marked eosinophilia),

worsening problems with breathing, nasal congestion, heart problems, pain, numbness, tingling in the arms and legs (signs of so-called “Churg-Strauss syndrome or hypereosinophilic syndrome”).

- Low blood platelet count with symptoms such as bleeding or bruising more easily than normal.
- Development of any of the following symptoms, especially if in combination: joint pain with or without swelling or stiffness, rash, fever, swollen lymph nodes, muscle pain, (signs of serum sickness).

If you experience any of these, tell a doctor or nurse straight away.

Other side effects include:

Very common side effects

- fever (in children)

Common side effects

- reactions at the injection site including pain, swelling, itching and redness
- pain in the upper part of the tummy (in children)
- headache (very common in children)

Uncommon side effects

- feeling dizzy, sleepy or tired
- tingling or numbness of the hands or feet
- fainting, low blood pressure while sitting or standing (postural hypotension), flushing
- sore throat, coughing, acute breathing problems
- feeling sick (nausea), diarrhoea, indigestion
- itching, hives, rash, increased sensitivity of the skin to sun
- weight increase
- flu-like symptoms
- swelling arms

Rare side effects

- parasitic infection

Not known

- joint pain, muscle pain and joint swelling
- hair loss

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE XOLAIR**

- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light.
- Store in a refrigerator (2°C – 8°C). Do not freeze.
- Do not use any pack that is damaged or shows signs of tampering.

## **6. FURTHER INFORMATION**

### **What Xolair contains**

- The active substance is omalizumab. One syringe of 0.5 ml solution contains 75 mg omalizumab. One syringe of 1 ml solution contains 150 mg omalizumab.
- The other ingredients are L-arginine hydrochloride, L-histidine hydrochloride, L-histidine,

Polysorbate 20 and water for injections.

### **What Xolair looks like and contents of the pack**

Xolair solution for injection is supplied as a clear to opalescent, slightly yellow to brown solution in a pre-filled syringe, and is available as 75 mg and 150 mg solution for injection.

Xolair 75 mg solution for injection is available in packs containing 1 pre-filled syringe and in multipacks comprising 4 or 10 intermediate packs, each containing 1 pre-filled syringe.

Xolair 150 mg solution for injection is available in packs containing 1 pre-filled syringe and in multipacks comprising 4 or 10 intermediate packs, each containing 1 pre-filled syringe.

Not all pack sizes may be marketed in your country.

### **Marketing Authorisation Holder**

Novartis Europharm Limited  
Wimblehurst Road  
Horsham  
West Sussex, RH12 5AB  
United Kingdom

### **Manufacturer**

Novartis Pharma GmbH  
Roonstrasse 25  
D-90429 Nuremberg  
GERMANY

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

### **België/Belgique/Belgien**

Novartis Pharma N.V.  
Tél/Tel: +32 2 246 16 11

### **Luxembourg/Luxemburg**

Novartis Pharma N.V.  
Tél/Tel: +32 2 246 16 11

### **България**

Novartis Pharma Services Inc.  
Тел.: +359 2 489 98 28

### **Magyarország**

Novartis Hungária Kft. Pharma  
Tel.: +36 1 457 65 00

### **Česká republika**

Novartis s.r.o.  
Tel: +420 225 775 111

### **Malta**

Novartis Pharma Services Inc.  
Tel: +356 2298 3217

### **Danmark**

Novartis Healthcare A/S  
Tlf: +45 39 16 84 00

### **Nederland**

Novartis Pharma B.V.  
Tel: +31 26 37 82 111

### **Deutschland**

Novartis Pharma GmbH  
Tel: +49 911 273 0

### **Norge**

Novartis Norge AS  
Tlf: +47 23 05 20 00

### **Eesti**

Novartis Pharma Services Inc.  
Tel: +372 66 30 810

### **Österreich**

Novartis Pharma GmbH  
Tel: +43 1 86 6570

### **Ελλάδα**

Novartis (Hellas) A.E.B.E.  
Τηλ: +30 210 281 17 12

### **Polska**

Novartis Poland Sp. z o.o.  
Tel.: +48 22 375 4888

**España**

Novartis Farmacéutica, S.A.  
Tel: +34 93 306 42 00

**France**

Novartis Pharma S.A.S.  
Tél: +33 1 55 47 66 00

**Ireland**

Novartis Ireland Limited  
Tel: +353 1 260 12 55

**Ísland**

Vistor hf.  
Sími: +354 535 7000

**Italia**

Novartis Farma S.p.A.  
Tel: +39 02 96 54 1

**Κύπρος**

Novartis Pharma Services Inc.  
Τηλ: +357 22 690 690

**Latvija**

Novartis Pharma Services Inc.  
Tel: +371 67 887 070

**Lietuva**

Novartis Pharma Services Inc.  
Tel: +370 5 269 16 50

**Portugal**

Novartis Farma - Produtos Farmacêuticos, S.A.  
Tel: +351 21 000 8600

**România**

Novartis Pharma Services Romania SRL  
Tel: +40 21 31299 01

**Slovenija**

Novartis Pharma Services Inc.  
Tel: +386 1 300 75 50

**Slovenská republika**

Novartis Slovakia s.r.o.  
Tel: +421 2 5542 5439

**Suomi/Finland**

Novartis Finland Oy  
Puh/Tel: +358 (0)10 6133 200

**Sverige**

Novartis Sverige AB  
Tel: +46 8 732 32 00

**United Kingdom**

Novartis Pharmaceuticals UK Ltd.  
Tel: +44 1276 698370

**This leaflet was last approved in 02/2012**

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>

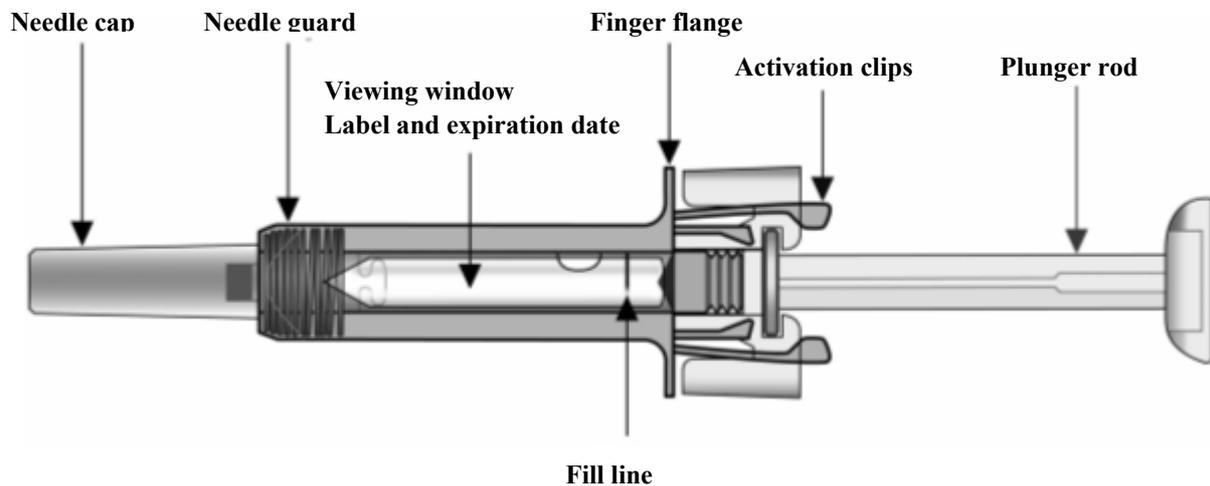
## INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only:

Before using the syringe, please read the following information carefully.

Each Xolair pack contains a pre-filled syringe individually sealed in a plastic wrapper.

### Parts of the pre-filled syringe

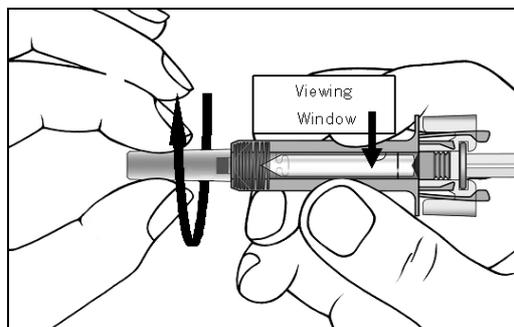


**Xolair syringes are intended to be used by a healthcare professional only.**

### Preparing the syringe for use

Prior to completion of the injection, avoid contact with the device activation clips (see first illustration) to keep from prematurely covering the needle with the needle guard.

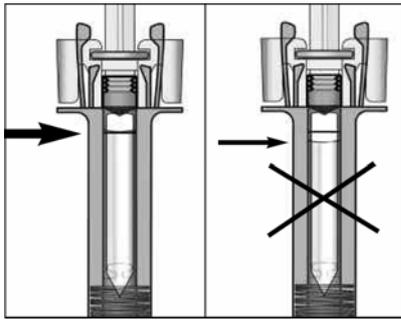
1. Take the box containing the syringe out of the refrigerator and leave it for about 20 minutes so that it reaches room temperature (leave the syringe in the box to protect it from light).
2. If necessary, the syringe can be returned to the refrigerator for use at a later time, but this must not be done more than once. The cumulative time during which the syringe is kept at room temperature must not exceed 4 hours.
3. When you are ready to use the syringe, wash your hands thoroughly with soap and water.
4. Clean the injection site.
5. Remove the plastic tray from the box, peel back the paper cover, and remove the syringe.
6. Inspect the syringe. **DO NOT USE** if it is broken or if the liquid looks cloudy or contains particles. In all these cases, return the entire pack to the pharmacy.
7. Holding the syringe horizontally (as shown below), look into the viewing window to check the dose (75 mg or 150 mg) of medicine and the expiry date printed on the label. Note: Rotate the inner part of the syringe assembly as shown below so that the label can be read in the viewing window.



8. Hold the syringe vertically with the plunger uppermost and tap the side of the syringe against your finger to allow the air bubble to rise.

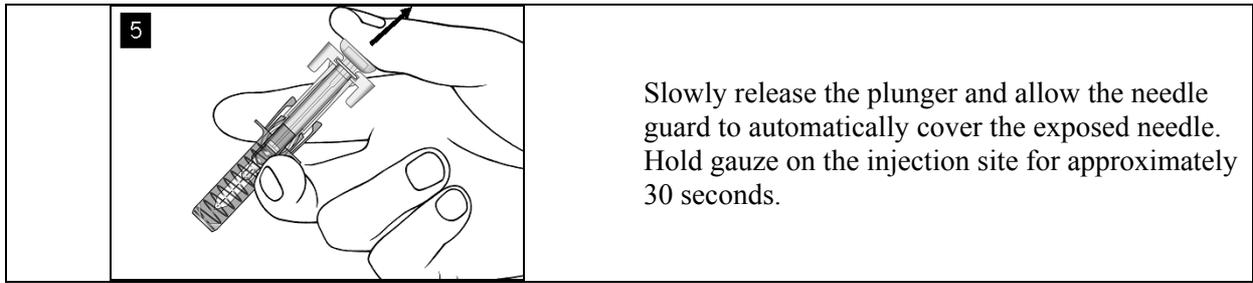
**DO NOT USE** if the product has expired or if the dose is incorrect. In both these cases, return the entire pack to the pharmacy.

9. Check to see if the liquid level is at or above the minimum fill line. If the liquid is below the fill line, return the entire pack to the pharmacy.



### Using the syringe

	<p>Holding the syringe with the needle pointing upwards, carefully pull off the needle cap from the syringe and discard it. Do not touch the exposed needle. Then, gently tap the syringe with your finger until the air bubble rises to the top of the syringe without inadvertently expelling solution.</p>
	<p>Gently pinch the skin at the injection site and insert the needle.</p>
	<p>Holding onto the finger flange, slowly depress the plunger as far as it will go. If any solution leaks from the injection site, insert the needle further.</p>
	<p>Keeping the plunger fully depressed, carefully lift the needle straight out from the injection site.</p>



**Disposal instructions**

Dispose of the used syringe immediately in a sharps container.