

Important information*

Allergic reactions, including anaphylaxis

*This booklet is intended for patients who have been prescribed Xolair (omalizumab) for severe allergic asthma.

This medicine is used to prevent asthma from getting worse by controlling symptoms of severe allergic asthma in adults, adolescents 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 and beta-agonist inhalers.

This guide is not intended to take the place of your Xolair leaflet. Please read your Xolair package leaflet carefully before you start using this medicine, as it contains important information for you, such as a full list of possible side effects. If you have any further questions, speak to your doctor, pharmacist or nurse.

Adverse event reporting information can be found on the final page of this guide.

 **NOVARTIS**

This material was created and funded by Novartis.





Be aware of allergic reactions and anaphylaxis

Xolair (omalizumab) contains a protein, and proteins can cause allergic reactions in some people. Symptoms of an allergic reaction usually develop within a few minutes of injection, although they can develop gradually over a period of several hours.

Common symptoms of an allergic reaction include:

- Raised, itchy, red rash (hives)
- Swollen lips, tongue, eyes or face
- Wheezing, chest tightness and cough
- Stomach pain, feeling sick, vomiting or diarrhoea

In rare cases, these allergic reactions may be severe (sometimes called anaphylaxis). If you have a history of severe allergic reactions unrelated to Xolair you may be more at risk of developing a severe allergic reaction following use of Xolair.

If you have a known history of anaphylaxis, the first 3 doses of Xolair must be administered by a health care professional.

Please note that the list of symptoms and serious conditions related to treatment with Xolair listed here is not exhaustive. Xolair can potentially cause other serious side effects. Other serious side effects: swelling, pain or rash around blood or lymph vessels, worsening problems with breathing, nasal congestion, heart problems, pain, numbness, tingling in arms and legs, bleeding or bruising more easily than normal, joint pain with or without swelling or stiffness, rash, fever, swollen lymph nodes and muscle pain. You must look out for signs of these conditions while you use Xolair. Seek medical help immediately if you notice any signs indicating serious side effects which are not discussed here. Such signs are listed under 'Serious side effects' in section 4 of the patient information leaflet.

Symptoms of severe allergic reactions (including anaphylaxis) include any of the above symptoms, plus:

- Swelling of the mouth, throat or other parts of the body
- Difficulty breathing
- Dizziness or light-headedness
- Confusion
- Blue skin tone or lips
- Collapsing and losing consciousness
- Fast heartbeat

How common are severe allergic reactions?

Anaphylaxis, a form of severe allergic reaction, is rare in Xolair patients, occurring in less than 2 in 1000 people, but it is important that you know what to do just in case.

2 in 1000

If you have any symptoms of an allergic reaction after using Xolair, seek medical attention immediately.




When could allergic reactions occur?

Symptoms of an allergic reaction usually develop within minutes of injection although they can develop gradually over a period of several hours.

The majority of anaphylactic reactions occur within THE FIRST 3 DOSES of Xolair, which is why these need to be given or supervised by your healthcare practitioner.

It is important that you receive training from your doctor in how to recognise early symptoms of severe allergic reactions, and how to manage these reactions if they occur, before you inject Xolair yourself or before a non-healthcare professional gives you a Xolair injection.



What should I do if I think I am having a severe allergic reaction?

If you experience any signs or symptoms of a severe allergic reaction you need to seek medical attention immediately.

- 1** If your doctor has provided you with an adrenaline autoinjector, follow the instructions on the autoinjector
- 2** Call 999 for an ambulance and say that you think you're having a severe allergic reaction to your Xolair injection
- 3** Lie down flat, unless you have trouble breathing. If you are having difficulty breathing, sit up instead as this can help make breathing easier
- 4** Tell your doctor or nurse that you think you have had a severe allergic reaction to your Xolair injection
- 5** Antihistamine medicines may provide relief for mild-moderate allergic reactions

Please note that this list is not exhaustive; please refer to Section 4 of your patient information leaflet for further information on serious allergic reactions.

It is a good idea to also let your friends, family and colleagues know ahead of injecting that you could be at risk of severe allergic reactions after a Xolair injection. Show them this leaflet so that they can familiarise themselves with the signs and symptoms of such a reaction and learn how to deal with it.

When do I need to contact a healthcare professional?

Seek medical attention immediately if you experience signs or symptoms of a severe allergic reaction or any other serious side effects as listed in the patient information leaflet.

If you experience a mild-moderate allergic reaction, it is not necessary for you to contact your doctor or nurse straight away.

However, you should make your doctor or nurse aware of any mild-moderate allergic reactions before it is time to inject your next dose of Xolair.

If you experience any other adverse events after using Xolair, tell your doctor or nurse at your next appointment.



Useful contacts

My specialist

Name:

Contact details:

My nurse

Name:

Contact details:

My local doctor

Name:

Contact details:

My pharmacist

Name:

Contact details:

Sources:

Omalizumab and the risk of an allergic reaction (anaphylaxis).

Available at: <https://www.ouh.nhs.uk/patient-guide/leaflets/files/55474Pomalizumab.pdf>.

Accessed: October 2023.

Treatment Allergies. Available at: www.nhs.uk/conditions/allergies/treatment/.

Accessed: October 2023.

Treatment Anaphylaxis. Available at: www.nhs.uk/conditions/anaphylaxis/treatment/.

Accessed: October 2023.

Xolair® Summary of Product Characteristics.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed on the package leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>. By reporting side effects you can help to provide more information on the safety of this medicine.

Date of preparation: October 2023

303432

 NOVARTIS


omalizumab