

The essentials

This booklet is intended for patients that have been prescribed Xolair (omalizumab) for chronic spontaneous urticaria (CSU).

This medicine is used to treat chronic spontaneous urticaria in adults and adolescents (12 years of age and older) who are already receiving antihistamines but whose CSU symptoms are not well controlled by these medicines.

Always refer to the patient information leaflet for information about your treatment.

Please find full information on how to report a side effect on the last page.

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About chronic spontaneous urticaria

What is chronic spontaneous urticaria?

Chronic spontaneous urticaria (CSU) is a skin condition that usually presents as hives (a red, itchy rash), swelling in the deeper layers of the skin (angioedema), or both.

Chronic Spontaneous Urticaria

Hives	Raised
	Red
	Itchy or sometimes burning
	No known trigger
Angioedema	Swelling in the deeper layers of the skin
	Eyelids and lips commonly affected
	Genitals, tongue, hands and feet can also be affected
	Usually resolves in 72 hours

These symptoms appear without warning, last for 6 weeks or more and can suddenly reappear at any time.

Unlike a lot of conditions where hives are a symptom, CSU often has no identifiable cause or trigger.

Underneath the skin

Urticaria is caused by increased levels of histamine – a chemical released by mast cells in your immune system.

Normally, histamine is released in response to a trigger, such as a mosquito bite. In CSU, however, histamine is released without an obvious cause or trigger.

It is the actions of histamine underneath the skin that leads to the symptoms of CSU:

- Histamine relaxes blood vessels, making them wider
- This releases fluid from the blood vessels into the skin, which presents as angioedema or hives
- This also brings blood closer to the surface of the skin, making the hives look red
- Histamine also activates nerves in the skin, creating an itchy sensation

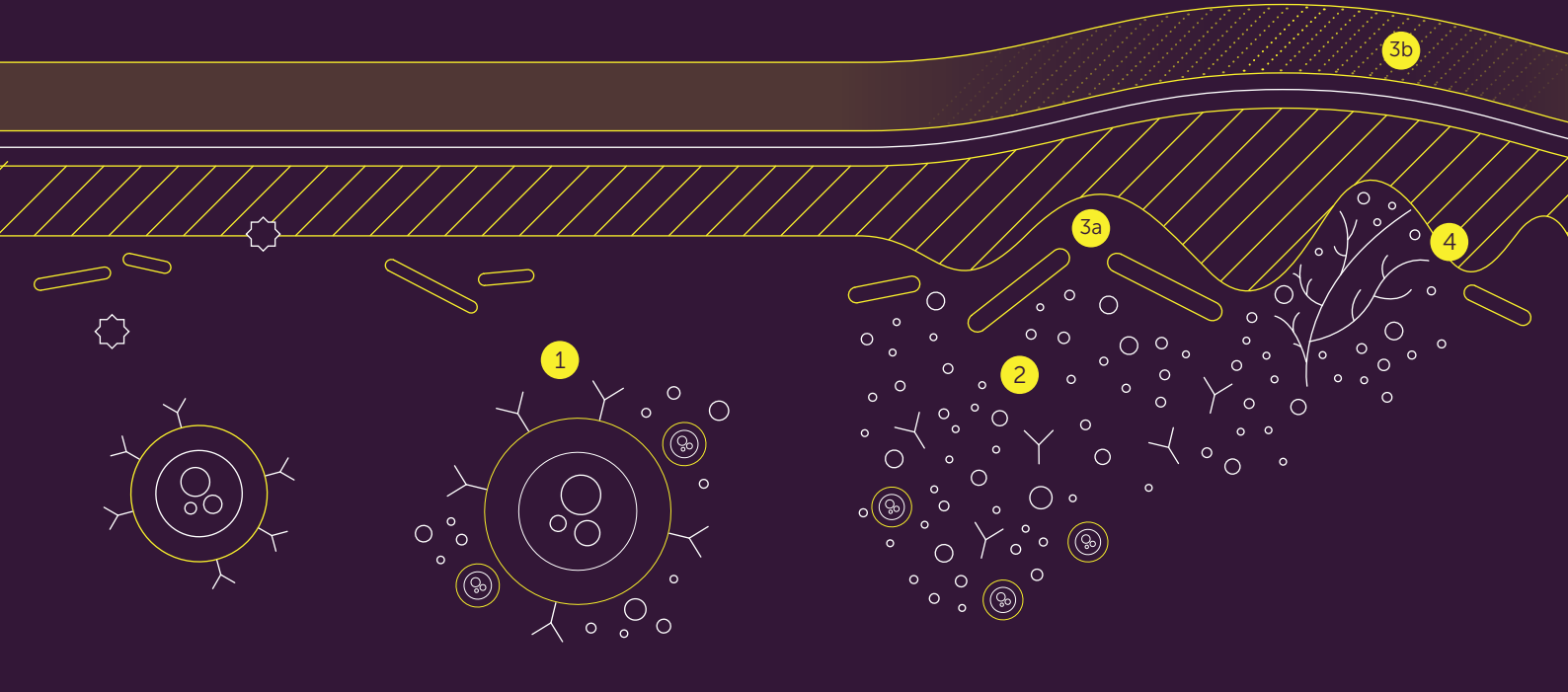
1 Histamine is released from mast cells without an obvious cause.

2 Histamine relaxes blood vessels, making them wider.

3a Fluid is released from the blood vessels, creating angioedema or hives.

4 Histamine activates nerves in the skin, creating an itchy sensation.

3b Blood is brought closer to the surface of the skin, making it appear red.



 Mast cells

 IgE

 Histamine

 Redness

 Blood vessel

 Nerves

Diagnosing chronic spontaneous urticaria

To help diagnose CSU your doctor or nurse will usually:

- Review your medical history to check if you are prone to allergies or other skin conditions
- Ask you to keep a symptom diary
- Perform a physical examination which may also include skin and blood tests

Treating chronic spontaneous urticaria

Unlike urticaria stemming from known causes, with CSU there is often no apparent cause or trigger – so managing the condition by controlling lifestyle factors isn't possible.

- 1 Antihistamines are the first step in the treatment of urticaria – but around half of people with CSU find that their symptoms don't respond sufficiently to treatment.
- 2 Xolair (omalizumab) is prescribed as an add-on treatment for people 12 years of age and older with CSU with an inadequate response to antihistamine treatment.

What can you expect from Xolair?

Xolair works by blocking a substance called immunoglobulin E (IgE), which is produced by the body. IgE contributes to a type of inflammation that plays a key role in causing allergic asthma, chronic rhinosinusitis with nasal polyps and CSU.

The **weekly Urticaria Activity Score (UAS7)** measures the number of hives and the severity of itch you experience over a 24-hour period and the **Dermatology Life Quality Index (DLQI)** assesses how your urticaria affects your day-to-day life.

You can find more information on how these scores are calculated and keep track of your own CSU symptoms, and any impact they have on your life, in booklet 3 of this pack.

For information about potential side effects, please refer to the patient information leaflet included in the box with your injection.

*Weekly Urticaria Activity Score = 0; **Dermatology Life Quality Index = 0/1.

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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.

For full details about Xolair, please refer to your patient information leaflet.

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