

ILT 101 for the treatment of amyotrophic lateral sclerosis (ALS)

Information for patients

This leaflet provides information about a medication called ILT 101 for people with amyotrophic lateral sclerosis (ALS), the most common type of motor neuron disease (MND).

Read all of this leaflet carefully before you are given this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any more questions, please do not hesitate to speak to your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, please talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

www.kch.nhs.uk

Before you start treatment

Why am I being invited to take ILT 101?

You are being invited to take ILT-101 – an experimental, unlicensed treatment for ALS – because you took part in the MIROCALS clinical trial. Although ILT-101 has been through two clinical trials, it is not yet proven to benefit people with ALS and has not been licensed for this use by the UK regulators. Because it is an experimental medicine, we do not have full knowledge of its safety and there may be unexpected side effects.

What is ILT 101?

ILT 101 is also known as aldesleukin. It is a synthetic protein, very similar to a protein produced by your body called interleukin-2 (IL-2). This protein is part of your immune system.

What does ILT 101 do?

IL2 stimulates a group of white blood cells in your body known as regulatory T cells – also called Tregs – which help to control inflammation. Inflammation is thought to contribute to ALS progression in your brain and spinal cord. Tregs are thought to play a part in protecting nerve cells against damage in ALS.

Aldesleukin is already used at higher doses to treat certain forms of cancer. At lower doses, its use in the treatment of immune system diseases is promising. The number of Tregs in the blood increases and inflammation is reduced. Helping Tregs to reduce inflammation in the brain and spinal cord may slow down the progress of ALS.

The safety and effectiveness of low-dose aldesleukin in treating ALS has been tested in a small-scale study. These have also been tested in a larger study, but the results are not yet known.

How will I be given the treatment?

You will have an ILT 101 injection once a day for five days every four weeks. You can have the injections in a hospital, in an outpatients department or at home. Follow all the instructions given to you by your doctor or nurse carefully. There is also some general advice on pages 4 and 5.

Do I have to have this treatment?

You do not have to have this treatment. It is entirely up to you whether you decide to go ahead and have the injections. If you do decide to have the ILT 101 injections, your doctor will discuss the treatment with you and only proceed if you agree. They will then write in your clinical notes that you have agreed. This is called 'giving informed consent'.

You should make your decision only:

1. After your doctor has explained the treatment to you.
2. If you understand the aim of the treatment and its risks.
3. If you are willing to do what is asked of you for safety monitoring while having the treatment.

Can I have this treatment if I am pregnant or breast feeding?

Pregnancy: Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant. They will discuss the risks and benefits of taking ILT 101 during pregnancy.

Contraception: Both male and female patients should use effective contraception while being treated with ILT 101 in order to prevent pregnancy.

Breastfeeding: You should not breast feed while taking ILT 101

Can I have this treatment if I am taking riluzole?

You can have this treatment whether or not you are taking riluzole. In a small-scale study to assess the safety of taking low-dose IL2 combined with riluzole, none of the 36 participants – who were treated for three months (three cycles) – had any serious side effects.

A larger study of 220 people with ALS testing this combination of drugs reported no major safety problems, although its full results are not yet known.

What happens before I start this treatment?

You may have tests before you start treatment. We will ask you to come to the clinic or go to your GP practice every three months for safety bloods to be taken and for monitoring.

You should also contact your GP or your prescribing neurologist if you have any concerns about this treatment at any time.

What are the risks?

You may have side effects (unwanted drug reactions) while on this medication. Please tell your specialist team if you have any suspected side effects.

As with any medication, these side effects may be mild or serious. Some will go away as soon as you stop taking the drug. Rarely, they can be serious, prolonged or might never go away. From what we know of the side effects of low-dose IL2, you are very unlikely to have persisting serious unwanted drug reactions, but we will monitor you very carefully.

You can contact your MND doctor at any time if you are at all worried about your symptoms. Their details are on your clinic letter.

The following list shows the most frequently reported and observed side effects (experienced by more than one in ten patients) in six previous studies of the treatment and which included over 100 patients with diseases other than ALS/with other diseases as well as ALS.

None of these were serious and all were mild, brief and resolved either on their own or with medication.

- Local reaction at the injection site (about half of people treated).
- Fatigue/feeling weak (about a quarter of people treated).
- Flu-like syndrome including chills, fever and muscle pain (about a quarter of people treated).
- Nausea/feeling sick (about one in six of people treated).

You may have other side effects that are not yet known. For example, all drugs can cause an allergic reaction in some patients. Certain problems can be dangerous if not treated quickly, so call your specialist doctor right away if you:

- feel very tired or faint
- feel pain or sick in your stomach and do not want to eat
- bruise easily or develop itching
- have yellow eyes or skin, or dark urine
- become confused.

If you have certain serious problems – such as an allergic reaction, swelling, difficulty breathing, a bad skin rash, liver or kidney damage, or changes in your heart rhythm – we may ask you to come back to the clinic for more assessments, which may include more blood tests. Your specialist doctor will explain these tests to you if you need them. You may also need to stop taking this drug after talking with your specialist doctor.

What are the benefits of this medication?

ILT 101 increases the number of Tregs in your blood. This helps to reduce inflammation in your brain and spinal cord and may slow down the progress of ALS.

Are there any alternatives?

The only drug treatment available in the UK shown to benefit people with MND is riluzole. This will be prescribed either by the specialist doctor with the support of your GP or arranged through a referring doctor. Riluzole was shown to alter the rate at which MND progresses in a study where people with ALS were either treated with riluzole or a placebo over a period of 18 months.

Your specialist doctor can tell you about other treatment choices for your ALS.

You may choose to:

- continue to get regular care from your doctor
- take part in a clinical trial
- have no treatment at this time.

Talk with your specialist doctor about your choices.

After you start treatment

How do I store ILT 101?

- Keep it out of the sight and reach of children.
- Do not use it after the expiry date shown on the pack after 'Exp'. The expiry date refers to the last day of that month.
- Store the unopened vials in a refrigerator at 2°C to 8°C. Do not freeze.
- Store them in the original packaging in order to protect them from light.

What should I do if I have taken too much ILT 101?

If you think you have taken too much ILT 101, contact your doctor or nurse immediately.

What should I do if I miss a dose?

If you forget or miss a dose, do not take a double dose and take your next planned dose as usual.

What medicines should I avoid while having this treatment?

Please talk with your MND doctor before you take **any** other medications, including having vaccinations.

Do I have to keep taking ILT 101?

You can stop taking the medication at any time, without giving a reason. Your decision will not affect your future medical care.

We will share with you any new information that becomes available that might affect your choice to keep taking the medication. This might include:

- safety issues with the drug
- evidence that it may not work
- another drug becomes available that may help treat your condition better.

Will you ask me to stop having this treatment?

We may ask you to stop having this treatment if:

- the results of certain tests show that you are not right for this drug

- you develop any new health problems while taking this unlicensed medication
- you become pregnant or decide that you want to become pregnant
- your doctor thinks it is in your best interest to stop.

Who can I contact with queries and concerns?

Please talk to your specialist doctor or nurse about any questions or concerns you have about this treatment. You can also call King's College Hospital MND service:

Prof Ammar Al-Chalabi

Tel: **020 7848 5172** in business hours, Monday to Friday, 9am – 5pm

Nurse Theresa Chiwera

Tel: **020 7848 5354** in business hours Monday to Friday, 9am – 5pm

Sharing your information

We have teamed up with Guy's and St Thomas' Hospitals in a partnership known as King's Health Partners Academic Health Sciences Centre. We are working together to give our patients the best possible care, so you might find we invite you for appointments at Guy's or St Thomas'. To make sure everyone you meet always has the most up-to-date information about your health, we may share information about you between the hospitals.

Care provided by students

We provide clinical training where our students get practical experience by treating patients. Please tell your doctor or nurse if you do not want students to be involved in your care. Your treatment will not be affected by your decision.

PALS

The Patient Advice and Liaison Service (PALS) is a service that offers support, information and assistance to patients, relatives and visitors. They can also provide help and advice if you have a concern or complaint that staff have not been able to resolve for you. They can also pass on praise or thanks to our teams.

PALS at King's College Hospital, Denmark Hill, London SE5 9RS

Tel: 020 3299 3601

Email: kch-tr.palsdh@nhs.net

If you would like the information in this leaflet in a different language or format, please contact our Communications and Interpreting telephone line on 020 3299 4826 or email kch-tr.accessibility@nhs.net