Package leaflet: Information for the patient

Tepkinly 48 mg solution for injection
epcoritamab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Tepkinly is and what it is used for

What Tepkinly is

Tepkinly contains the active substance epcoritamab, which is a type of protein called an antibody designed to kill cancer cells. Tepkinly is used to treat adult patients who have a blood cancer called diffuse large B-cell lymphoma (DLBCL) when the disease has come back or did not respond to previous treatment and who have received at least two prior therapies.

How Tepkinly works

Epcoritamab is specifically designed to help your own immune system to attack cancer (lymphoma) cells. Epcoritamab acts by attaching to your body's immune cells and cancer cells, bringing them together, so that your immune system can destroy the cancer cells.

2. What you need to know before you use Tepkinly

Do not use Tepkinly

If you are allergic to epcoritamab or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor or nurse before you are given Tepkinly.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Tepkinly if you
- have current or past problems with your nervous system – such as seizures
- have an infection
- are due to have a vaccine or you know you may need to have one in the near future.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before you are given Tepkinly.

Tell your doctor straight away if you get symptoms of any of the side effects listed below, during or after treatment with Tepkinly. You may need additional medical treatment. The symptoms of each side effect are listed in section 4.

- **CRS (cytokine release syndrome) –** a condition associated with medicines that stimulate T cells.
  − Before each injection under the skin, you may be given medicines, which help reduce possible side effects of cytokine release syndrome.
- **ICANS (immune effector cell associated neurotoxicity syndrome)-** Symptoms may be difficulty speaking and/or writing, drowsiness, confusion/disorientation, muscle weakness, seizures, and memory loss.
- **TLS (tumour lysis syndrome)** – some people may get unusual levels of some salts in the blood – caused by the fast breakdown of cancer cells during treatment. This is called TLS.
  - Your doctor or nurse will do blood tests to check for this condition. Before each injection under the skin, you should be well-hydrated and may be given other medicines that can help reduce high levels of uric acid and help reduce possible effects of tumour lysis syndrome.
- **Tumour flare** – as your cancer is destroyed, it may react and appear to get worse – this is called 'tumour flare reaction'.
- **Infections** – you may get signs of infection, which can vary depending on where in the body the infection is.

Children and adolescents

Tepkinly should not be given to children and adolescents under 18 years, as there is no information about its use in this age group.

Other medicines and Tepkinly

Tell your doctor or pharmacist if you are taking or using, have recently taken or used, or might take or use any other medicines. This includes medicines obtained without a prescription and herbal medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not have Tepkinly during pregnancy, as it may affect your unborn baby.

Contraception

If you are a woman of child-bearing potential, you must use effective contraception to avoid becoming pregnant while taking Tepkinly and for at least 4 months after your last dose of Tepkinly. If you become pregnant during this time, you must tell your doctor immediately.

Talk to your doctor or nurse about suitable methods of contraception.

Pregnancy

Do not use Tepkinly during pregnancy and if you are of childbearing potential and not using contraception. Pregnancy must be ruled out before treatment. This is because Tepkinly may affect your unborn baby. Tell your doctor immediately if you become pregnant or think you may be pregnant during treatment with Tepkinly.

Breast-feeding

You must not breast-feed during treatment with Tepkinly and for at least 4 months after the last dose. It is not known whether Tepkinly passes into breast milk and could therefore affect your baby.

Fertility

The effect of Tepkinly on male and female fertility is unknown.

Driving and using machines

Tepkinly may affect your ability to drive, cycle or use tools and machines. If you feel any symptom that makes you feel unwell, do not drive, cycle or use tools or machines until you feel better. See section 4 for more information about side effects.

Tepkinly contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

Tepkinly contains sorbitol

This medicine contains 21.9 mg sorbitol in each vial, which is equivalent to 27.33 mg/ml.

3. How Tepkinly will be given

A doctor experienced in treating cancer will take care of your treatment. Follow the treatment schedule explained to you by your doctor.

Tepkinly will be given to you by a doctor or nurse and it will be given as an injection under your skin. Tepkinly will be given to you in cycles of 28 days, on a dosing schedule given to you by your doctor.

You will be given Tepkinly according to the following schedule

Cycle	**Dosing Schedule**
Cycles 1 to 3	Weekly
Cycles 4 to 9	Every two weeks
Cycles 10 and beyond	Every four weeks

You may be given other medicines before Tepkinly. This is to help prevent reactions associated with cytokine release syndrome.
These other medicines may include

- Corticosteroids- such as prednisolone or equivalent
- An antihistamine – such as diphenhydramine
- Paracetamol

The first full dose (48 mg) of Tepkinly will be given to you on Cycle 1 Day 15. Your doctor will monitor how your treatment is working and ask you to stay in a hospital for 24 hours after the first full dose (48 mg) because this is when reactions such as CRS, ICANS and fever are most likely to happen.

You will be given Tepkinly for as long as your doctor thinks you are benefitting from the treatment.

Your doctor may delay or completely stop your treatment with Tepkinly if you have certain side effects.

If you forget to use Tepkinly
If you forget or miss your medical appointment, make another one straight away. For the treatment to be fully effective, it is very important not to miss a dose.

If you stop using Tepkinly

Do not stop treatment with Tepkinly unless you have discussed this with your doctor. This is because stopping treatment may make your condition worse.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor straight away if you notice any of the symptoms of the following serious side effects. You may only get one or some of these symptoms.

Cytokine release syndrome (CRS) (Very common: may affect more than 1 in 10 people)
Symptoms can include

- fever
- vomiting
- dizziness or light-headedness
- chills
- fast heartbeat
- difficulty breathing/shortness of breath
- headache

Immune effector cell-associated neurotoxicity syndrome (ICANS) (Common: may affect up to 1 in 10 people)

- effects on your nervous system, the symptoms of which can occur days or weeks after you receive the injection, may initially be subtle. Some of these symptoms may be signs of a serious immune reaction called “immune effector cell associated neurotoxicity syndrome” (ICANS).
  Symptoms of ICANS can include
  - difficulty speaking or writing
  - drowsiness
  - confusion/disorientation
  - muscle weakness
  - seizures
  - memory loss

Tumour lysis syndrome (TLS) (**Common:** may affect up to 1 in 10 people)
Symptoms can include

- fever
- chills
- vomiting
- confusion
- shortness of breath
- seizures
- irregular heartbeat
- dark or cloudy urine
- unusual tiredness
- muscle or joint pain

Tumour flare (Common: may affect up to 1 in 10 people)
Symptoms can include

- tender swollen lymph nodes
- chest pain
- cough or difficulty breathing
- pain at the site of the tumour

Febrile neutropenia (Common: may affect up to 1 in 10 people):
Symptoms can include

- fever due to infection (when you have low levels of white blood cells (shown in blood tests done by your doctor))

Other side effects
Very common: may affect more than 1 in 10 people

- pneumonia (lung infection)
- headache
- nausea
- diarrhoea
- vomiting
- injection site reactions
- fever
- tiredness
- pain in the belly area
- swelling

Shown in blood tests

- low levels of some white blood cells that fight infection (neutropenia)
- low number of red blood cells, which can cause tiredness, pale skin, and shortness of breath (anaemia)
- low platelet count, which may make you more likely to bruise or bleed (thrombocytopenia)

Common: may affect up to 1 in 10 people

- upper respiratory tract infections (infection of the airways)
- rash
- itching (pruritus)

Shown in blood tests

- low level of potassium, which can cause weakness, muscle cramps, tingling and heart rhythm changes
- low level of phosphates
- low level of magnesium
- an increase in liver tests, which may show problems with the liver

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Tepkinly

Tepkinly will be stored by the doctor, nurse, or pharmacist at the hospital or clinic. To correctly store Tepkinly

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the vial label and carton after EXP. The expiry date refers to the last day of that month.
- Store and transport refrigerated (2°C to 8°C).
- Keep the vial in the outer carton in order to protect from light.
- Do not freeze.
- Do not shake.

- If not used immediately, the prepared solution may be stored for up to 24 hours at 2°C to 8°C from the time of preparation.
- Within these 24 hours, the epcoritamab solution can be stored for 12 hours at room temperature from the start of dose preparation to administration.
- Allow the solution to warm to room temperature before using.

Your doctor, nurse, or pharmacist will throw away any unused medicine following local requirements. These measures will help protect the environment.

6. Contents of the pack and other information

What Tepkinly contains
- The active substance is epcoritamab. Each 0.8 ml vial contains 48 mg of epcoritamab at a concentration of 60 mg/ml.
- The other excipients are sodium acetate trihydrate, acetic acid, sorbitol (E420), polysorbate 80, water for injections (see section 2 “Tepkinly contains sodium” and “Tepkinly contains sorbitol”).

What Tepkinly looks like and contents of the pack

Tepkinly is a solution for injection. It is a colourless to slightly yellow solution provided in a glass vial.

Each carton contains 1 vial.

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This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency (MHRA) website: http://www.mhra.gov.uk There are also links to other websites about rare diseases and treatments.

To listen to or request a copy of this leaflet in <Braille>, <large print> or <audio>, please contact the Marketing Authorisation Holder.

The following information is intended for healthcare professionals only:

Tepkinly is prepared and administered as a subcutaneous injection.

Each vial of epcoritamab is intended for single use only.

Each vial contains an overfill that allows withdrawal of the labelled amount.

Epcoritamab must be prepared and administered by a healthcare professional using aseptic technique - **No dilution required**.

Tepkinly 48 mg vial is supplied as ready-to-use solution that does not need dilution prior to administration.

Filtration of the solution is not required. However, if the solution is filtered, do not use filters made of nylon.

Epcoritamab should be inspected visually for particulate matter and discolouration prior to administration. The solution for injection should be a colourless to slightly yellow solution. Do not use if the solution is discoloured, or cloudy, or if particles are present.

1) Prepare Tepkinly vial a) Retrieve one 48 mg Tepkinly vial with the **orange** cap from the refrigerator. b) Allow the vial to come to room temperature for no more than 1 hour. c) Gently swirl the Tepkinly vial. **DO NOT** invert, vortex or vigorously shake the vial.
2) Withdraw dose Withdraw 0.8 ml of Tepkinly from the vial into a syringe.
3) Label syringe Label the syringe with the dose strength (48 mg) and the time of day.
4) Discard the vial containing unused Tepkinly in accordance with local requirements.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.