

## Package leaflet: Information for the patient

# Tepkinly® 4 mg/0.8 ml concentrate for solution for injection

(epcoritamab)

<p><span>▼</span> 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.</p>
---

**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.

This product is called Tepkinly 4 mg/0.8 mL solution for injection but will be referred to as Tepkinly throughout the leaflet.

**What is in this leaflet**

- What Tepkinly is and what it is used for
- What you need to know before you use Tepkinly
- How Tepkinly will be given
- Possible side effects
- How to store Tepkinly
- Contents of the pack and other information

## 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

<p><b>Do not use Tepkinly</b></p> <p>If you are allergic to epcoritamab or any of the other ingredients of this medicine (listed in section 6).</p>
---

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.

<p><b>Other medicines and Tepkinly</b></p> <p>Tell your doctor, pharmacist or nurse before using Tepkinly 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.</p>
--

**Pregnancy, breast-feeding and fertility**

Read this entire section carefully before preparation of epcoritamab. **Certain doses** (the priming (0.16 mg) and intermediate dose (0.8 mg)) of epcoritamab require **dilution** prior to administration. Follow all preparation instructions as below, as improper preparation may lead to improper dose. Epcoritamab can be diluted using two different methods which are either the vial method or the syringe method.

Epcoritamab 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 diluted and administered by a healthcare professional using aseptic technique.

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

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.

<ul style="list-style-type: none"><li><b>CRS (cytokine release syndrome)</b> <ul style="list-style-type: none"><li>A condition associated with medicines that stimulate T cells.</li> <li>Before each injection under the skin, you may be given medicines, which help reduce possible side effects of cytokine release syndrome.</li></ul></li> <li><b>ICANS (immune effector cell associated neurotoxicity syndrome)</b> <ul style="list-style-type: none"><li>Symptoms may be difficulty speaking and/or writing, drowsiness, confusion/disorientation, muscle weakness, seizures, and memory loss.</li></ul></li> <li><b>TLS (tumour lysis syndrome)</b> <ul style="list-style-type: none"><li>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.</li> <li>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.</li></ul></li> <li><b>Tumour flare</b> <ul style="list-style-type: none"><li>As your cancer is destroyed, it may react and appear to get worse - this is called ‘tumour flare reaction’ .</li></ul></li> <li><b>Infections</b> <ul style="list-style-type: none"><li>You may get signs of infection, which can vary depending on where in the body the infection is.</li></ul></li> <li><b>Progressive multifocal leukoencephalopathy (PML)</b> <ul style="list-style-type: none"><li>Symptoms of this serious and potentially fatal brain condition may include blurred vision, loss of vision or double vision, difficulty speaking, weakness or clumsiness of an arm or a leg, a change in the way you walk or problems with your balance, personality changes, changes in thinking, memory and orientation leading to confusion. These symptoms may start several months after treatment has ended and they usually develop slowly and gradually over weeks or months. It is important that your relatives or caregivers are also aware of these symptoms, since they may notice symptoms that you are not aware of.</li></ul></li></ul>
---

**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.

<p><b>Materials needed to prepare Tepkinly 0.16 mg dose and Tepkinly 0.8 mg dose</b></p>
--

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

The following table outlines the materials needed for preparation of the 0.16 mg and 0.8 mg doses of Tepkinly using sterile vials.

<p><b>Materials needed to prepare Tepkinly 0.16 mg dose and Tepkinly 0.8 mg dose</b></p>	
<b>Priming dose (0.16 mg)</b>	<b>Intermediate dose (0.8 mg)</b>
4 mg/0.8 ml Tepkinly vial with <b>light blue</b> cap	4 mg/0.8 ml Tepkinly vial with <b>light blue</b> cap
0.9% sodium chloride injection	0.9% sodium chloride injection
Two empty sterile vials (10 or 20 ml vial size)	One empty sterile vial (10 or 20 ml vial size)

**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.

<p>You will be given Tepkinly according to the following schedule</p>	
<b>Cycle</b>	<b>Dosing Schedule</b>
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.

<p><b>Materials needed to prepare Tepkinly 0.16 mg dose and Tepkinly 0.8 mg dose</b></p>
--

<b>Priming dose (0.16 mg)</b>	<b>Intermediate dose (0.8 mg)</b>
Recommended syringe sizes	Recommended syringe sizes
<ul style="list-style-type: none"><li>Two 1 ml syringes</li> <li>One 3 ml syringe</li> <li>One 5 ml syringe</li> <li>One 10 ml syringe</li></ul>	<ul style="list-style-type: none"><li>Two 1 ml syringes</li> <li>One 5 ml syringe</li></ul>

**Preparation of diluted epcoritamab using the empty sterile vial method**

**0.16 mg priming dose preparation instructions - 2 dilutions required – empty sterile vial method**

Use an appropriately sized syringe, vial and needle for each transfer step.

- Prepare Tepkinly vial
- Retrieve one 4 mg/0.8 ml Tepkinly vial with the **light blue** cap from the refrigerator.
- Allow the vial to come to room temperature for no more than 1 hour.
- Gently swirl the Tepkinly vial.

**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.

<p><b>Cytokine release syndrome (CRS)</b></p> <p><b>(Very common:</b> may affect more than 1 in 10 people)</p> <p>Symptoms can include</p> <ul style="list-style-type: none"><li>fever</li> <li>vomiting</li> <li>dizziness or light-headedness</li> <li>chills</li> <li>fast heartbeat</li> <li>difficulty breathing/shortness of breath</li> <li>headache</li></ul>
---

**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))

<p><b>Materials needed to prepare Tepkinly 0.16 mg dose and Tepkinly 0.8 mg dose</b></p>
--

**DO NOT** invert, vortex or vigorously shake the vial.

2) Perform first dilution

- Label an appropriately sized empty vial as “**dilution A**”.
- Transfer **0.8 ml of Tepkinly** into the **dilution A** vial.
- Transfer **4.2 ml of sodium chloride 9 mg/ml (0.9%) sterile solution** into the **dilution A** vial. The initial diluted solution contains 0.8 mg/ml of epcoritamab.
- Gently swirl the **dilution A** vial for 30 – 45 seconds.

3) Perform second dilution

- Label an appropriately sized empty vial as “**dilution B**”.
- Transfer **2.0 ml of solution** from the **dilution A** vial into the **dilution B** vial. The **dilution A** vial is no longer needed and should be discarded.
- Transfer **8.0 ml of sodium chloride 9 mg/ml (0.9%) sterile solution** into the **dilution B** vial to make a final concentration of 0.16 mg/ml.
- Gently swirl the **dilution B** vial for 30 – 45 seconds.

4) Withdraw dose

Withdraw **1.0 ml of the diluted epcoritamab** from the **dilution B** vial into a syringe. The **dilution B** vial is no longer needed and should be discarded.

**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.
- Tepkinly 4 mg/0.8 ml is a concentrated solution and must be diluted prior to use.
- 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 dilution 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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

<p><b>Materials needed to prepare Tepkinly 0.16 mg dose and Tepkinly 0.8 mg dose</b></p>
--

5) Label syringe

Label the syringe with the product name, dose strength (0.16 mg), date and the time of day.

6) Discard the vial containing unused Tepkinly in accordance with local requirements.

**0.8 mg intermediate dose preparation instructions - 1 dilution required – empty sterile vial method**

Use an appropriately sized syringe, vial and needle for each transfer step.

- Prepare Tepkinly vial
- Retrieve one 4 mg/0.8 ml Tepkinly vial with the **light blue** cap from the refrigerator.
- Allow the vial to come to room temperature for no more than 1 hour.
- Gently swirl the Tepkinly vial.

**DO NOT** invert, vortex or vigorously shake the vial.

2) Perform dilution

- Label an appropriately sized empty vial as “**dilution A**”.
- Transfer **0.8 ml of Tepkinly** into the **dilution A** vial.
- Transfer **4.2 ml of sodium chloride 9 mg/ml (0.9%) sterile solution** into the **dilution A** vial to make a final concentration of 0.8 mg/ml.

## 6. Contents of the pack and other information

### What Tepkinly contains

- The active substance is epcoritamab. Each 0.8 ml vial contains 4 mg of epcoritamab at a concentration of 5 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 concentrate for solution for injection. It is a colourless to slightly yellow solution provided in a glass vial.

Each carton contains 1 vial.

### Manufacturer:

AbbVie S.r.l.  
S.R. 148 Pontina, km 52 SNC  
04011 Campoverde di Aprilia (LT)  
ITALY

**Procured from within the EU and repackaged for the PL Holder:** Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

PL 45763/1864

**POM**

Tepkinly® is a registered trademark of AbbVie Biotechnology Ltd

For any information about this medicine, please contact the local representative of the Product Licence Holder:

Abacus Medicine Ltd.  
tel: +44(0)2036301244  
email: MedInfo@abacusmedicine.co.uk  
or  
drugsafetyuk@abacusmedicine.co.uk

**This leaflet was last revised on 21.03.2025.**

**Blind or partially sighted?  
Is this leaflet hard to see or read?  
Call 02036301310  
or write to  
info@abacusmedicine.com to obtain the leaflet in a format suitable for you.**

d) Gently swirl the **dilution A** vial for 30 to 45 seconds.

3) Withdraw dose  
Withdraw **1.0 ml of the diluted epcoritamab** from the **dilution A** vial into a syringe. The **dilution A** vial is no longer needed and should be discarded.

4) Label syringe  
Label the syringe with the product name, dose strength (0.8 mg), date and the time of day.

5) Discard the vial and any unused portion of Tepkinly in accordance with local requirements.

### Preparation of diluted epcoritamab using the sterile syringe method

#### 0.16 mg priming dose preparation instructions – 2 dilutions required – sterile syringe method

Use an appropriately sized syringe and needle for each transfer step.

- 1) Prepare Tepkinly vial  
a) Retrieve one 4 mg/0.8 ml Tepkinly vial with the **light blue** 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** vortex or vigorously shake the vial.

- 2) Perform first dilution
  - a) Label an appropriately sized syringe as “**dilution A**”.
  - b) Withdraw **4.2 ml of sodium chloride 9 mg/ml (0.9%) sterile solution** into the **dilution A** syringe. Include approximately 0.2 ml air in the syringe.
  - c) In a new syringe labelled as “**syringe 1**”, withdraw **0.8 ml of epcoritamab**.
  - d) Connect the two syringes and push the **0.8 ml of epcoritamab** into the **dilution A** syringe. The initially diluted solution contains 0.8 mg/ml of epcoritamab.
  - e) Gently mix by inverting the connected syringes 180 degrees 5 times.
  - f) Disconnect the syringes and discard **syringe 1**.

- 3) Perform second dilution
  - a) Label an appropriately sized syringe as “**dilution B**”.
  - b) Withdraw **8 ml of sodium chloride 9 mg/ml (0.9%) sterile solution** into the **dilution B syringe**. Include approximately 0.2 ml air in the syringe.
  - c) Label another appropriately sized syringe as “**syringe 2**”.
  - d) Connect **syringe 2** to the **dilution A** syringe and transfer **2 ml of solution** into **syringe 2**. The **dilution A** syringe is no longer needed and should be discarded.
  - e) Connect **syringe 2** to the **dilution B** syringe and push the **2 ml of solution** into the **dilution B** syringe to make a final concentration of 0.16 mg/ml.
  - f) Gently mix by inverting the connected syringes 180 degrees 5 times.
  - g) Disconnect the syringes and discard **syringe 2**.

4) Withdraw dose  
Connect and transfer **1 ml of the diluted epcoritamab** from the **dilution B** syringe into a new syringe. The **dilution B** syringe is no longer needed and should be discarded.

5) Label syringe  
Label the syringe with the product name, dose strength (0.16 mg), date and the time of the day.

6) Discard the vial and any unused portion of Tepkinly in accordance with local requirements.

#### 0.8 mg intermediate dose preparation instructions -1 dilution required– sterile syringe method

Use an appropriately sized syringe and needle for each transfer step.

- 1) Prepare Tepkinly vial
  - a) Retrieve one 4 mg/0.8 ml Tepkinly vial with the **light blue** 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** vortex or vigorously shake the vial.

- 2) Perform dilution
  - a) Label an appropriately sized syringe as “**dilution A**”.
  - b) Withdraw **4.2 ml of sodium chloride 9 mg/ml (0.9%) sterile solution** into the **dilution A** syringe. Include approximately 0.2 ml air in the syringe.
  - c) In a new syringe labelled as “**syringe 1**”, withdraw **0.8 ml of epcoritamab**.
  - d) Connect the two syringes and push the **0.8 ml of epcoritamab** into the **dilution A** syringe to make a final concentration of 0.8 mg/ml.

e) Gently mix by inverting the connected syringes 180 degrees 5 times.  
f) Disconnect the syringes and discard **syringe 1**.

3) Withdraw dose  
Connect a new syringe to the **dilution A** syringe and transfer **1 ml of the diluted epcoritamab** into the new syringe. The **dilution A** syringe is no longer needed and should be discarded.

4) Label syringe  
Label the syringe with the product name, dose strength (0.8 mg), date and the time of day.

5) Discard the vial and any unused portion of 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.

