swissmedic

Summary report on authorisation dated 28 November 2025

Tepkinly® (active substance: epcoritamab)

Temporary indication extension in Switzerland: 19 August 2025

Solution for injection for the treatment of adults with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy

About the medicinal product

Tepkinly contains the active substance epcoritamab and is administered as an intravenous infusion.

Tepkinly received temporary authorisation on 15 February 2024 as monotherapy for the treatment of adults with a specific form of blood cancer called relapsed (recurrent) or refractory (progressive) diffuse large B-cell lymphoma (DLBCL) who have previously received two or more systemic therapies[1], including a CD20-targeted antibody therapy[2]. Furthermore, the cancer (DLBCL) must also have continued to progress despite previous specific CAR T-cell therapy[3] or patients must have been unsuitable for this treatment.

As a result of this indication extension of 19 August 2025, Tepkinly is now also temporarily authorised for the treatment of adults with another specific type of blood cancer called relapsed or refractory follicular lymphoma (FL). In this disease, B cells (a type of white blood cell) multiply and accumulate in the lymph nodes. Patients to be treated with Tepkinly must have undergone at least two previous systemic therapies, including a CD20-targeted antibody therapy and an alkylating agent[4] or lenalidomide.

Since DLBCL and FL are rare and life-threatening diseases, the medicine has been authorised as an orphan drug. "Orphan drug" is a designation given to medicinal products for rare diseases.

Tepkinly was authorised under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in another country with comparable medicinal product control.

[1] Systemic therapy: In contrast to local therapy (treatment at the site of the disorder), systemic therapy involves treatment of the entire body to eliminate a disorder.

[2] CD20-targeted antibody therapy: Treatment with special proteins (antibodies) that specifically recognise and combat cancer cells. They bind to a feature of malignant B cells named CD20 and help the immune system destroy these cells.

[3] CAR-T cell therapy: A specific form of immunotherapy in which the patient's own immune cells are genetically modified so they can recognise and specifically destroy cancer cells.

[4] Alkylating agents: Active substances used in chemotherapy which prevent cancer cells from dividing by disrupting their DNA.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland.

The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Tepkinly in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency EMA (EMEA/H/C/005985/II/0001) and has only conducted a limited scientific review.

Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report and summary report issued by the reference authority: www.ema.europa.eu

Mode of action

The active substance epcoritamab is a bi-specific antibody (an immunologically effective protein). Epcoritamab binds both to the tumour cells, by binding to the CD20 receptor (binding site) on the surface of B cells, and to the CD3 receptor on the surface of T cells (cells of the immune system). By binding simultaneously to CD20 on B cells and CD3 on T cells, there is direct contact between the tumour cells and T cells, leading to replication and activation of the T cells. Specific proteins that play a key role in immune defence are excreted as a result.
Thanks to this mechanism of action, the immune system can kill the target B cells and inhibit the growth of the cancer.

Administration

Tepkinly, containing the active substance epcoritamab, is a prescription-only medicine.

Tepkinly is available as a solution for injection containing 4 mg or 48 mg epcoritamab in 0.8 mL solution. It is injected subcutaneously, i.e. under the skin.

The dose is administered according to a specific schedule. The medication is administered weekly for the first three treatment cycles. In the following six cycles, administration is reduced to every two weeks. From the tenth cycle and for all subsequent cycles, Tepkinly is only administered once a month.

Treatment with Tepkinly is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments. It is administered in a setting with appropriate medical facilities for treating possible severe reactions.

Efficacy

The efficacy of Tepkinly was investigated in a study named GCT3013-01. In this study, Tepkinly was tested as monotherapy in patients with relapsed or refractory follicular lymphoma. These patients had already received at least two systemic therapies, one of which included an anti-CD20 antibody and either an alkylating agent or lenalidomide.

A total of 128 patients were enrolled in the study.

The study data showed an overall objective response rate (ORR)[5] of 83% and a median duration of response (DOR)[6] of 21.4 months.

Precautions, undesirable effects, & risks

Tepkinly must not be used in those who are hypersensitive to the active substance or any of the excipients.

Since Tepkinly may cause serious or life-threatening reactions such as cytokine release syndrome (CRS)[7] and neurological side effects, including immune effector cell-associated neurotoxicity syndrome (ICANS)[8], close monitoring is required.

The most common undesirable effects (affecting more than 20% of patients) were CRS, injection site reactions, fatigue, viral infections, neutropenia (reduction in certain white blood cells), musculoskeletal pain, fever and diarrhoea.

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The treatment options for patients with relapsed or refractory follicular lymphoma are currently limited, particularly after several therapies have been tried. Tepkinly, containing the active substance epcoritamab, offers a new treatment option that has demonstrated a high response rate and protracted duration of response in clinical trials.

Swissmedic agrees with the EMA's assessment that Tepkinly has a positive risk/benefit profile for patients with relapsed or refractory follicular lymphoma (FL) who have already undergone at least two previous systemic therapies, including a CD20-targeted antibody therapy and an alkylating agent or lenalidomide.

Swissmedic authorised this indication extension for Tepkinly temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation.

The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation without special conditions in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Tepkinly®

Healthcare professionals can answer any further questions.

[5] Objective response rate (ORR): The objective response rate describes the percentage of patients with a clinically relevant reduction in tumour size.

[6] Median duration of response (DOR): Period of time during which the disease responds to the treatment and does not progress again.

[7] CRS: Cytokine release syndrome is a systemic inflammatory response to the massive secretion of cytokines (proteins), which activate the white blood cells.

[8] ICANS: Immune effector cell-associated neurotoxicity syndrome is a complex of diverse neurological symptoms of varying intensity, such as impaired consciousness.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.