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Torisel (*temsirolimus*)

An overview of Torisel and why it is authorised in the EU

What is Torisel and what is it used for?

Torisel is a medicine used to treat patients with the following types of cancer:

- advanced renal cell carcinoma (a kidney cancer). 'Advanced' means that the cancer has started to spread;
- mantle cell lymphoma (a cancer of B cells, a type of white blood cell). Torisel is used in adults when the lymphoma has come back after previous treatment or if other treatments have not worked.

These diseases are rare, and Torisel was designated an 'orphan medicine' (a medicine used in rare diseases) on various dates. Further information on the orphan designations can be found on the European Medicines Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation (renal cell carcinoma: 6 April 2006, expired November 2017; mantle cell lymphoma: 6 November 2006).

Torisel contains the active substance temsirolimus.

How is Torisel used?

Torisel must be given under the supervision of a doctor who has experience in the use of cancer medicines. The medicine can only be obtained with a prescription.

Torisel is available as a concentrate and solvent that are made up into a solution for infusion (drip) into a vein. It is given as an infusion lasting 30 to 60 minutes. For renal cell carcinoma, the recommended dose of Torisel is 25 mg once a week, but a 10-mg dose is recommended in patients with severe liver problems who have high levels of platelets in the blood. For mantle cell lymphoma, the recommended dose is 175 mg once a week for three weeks, followed by weekly doses of 75 mg.

Patients are given an antihistamine injection to prevent an allergic reaction around 30 minutes before each dose of Torisel. Treatment with Torisel should continue until the medicine is no longer working or causes unacceptable side effects. Some side effects can be managed by interrupting treatment or reducing the dose.

For more information about using Torisel, see the package leaflet or contact your doctor or pharmacist.

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How does Torisel work?

The active substance in Torisel, temsirolimus blocks a protein called 'mammalian target of rapamycin' (mTOR). In the body, temsirolimus attaches to a protein inside cells to make a 'complex'. This complex then blocks mTOR. Since mTOR is involved in the control of cell division, Torisel prevents the division of cancer cells, slowing down the growth and spread of the cancer.

What benefits of Torisel have been shown in studies?

Advanced renal cell carcinoma

In advanced renal cell carcinoma, a main study involving 626 patients with poor prognosis found Torisel more effective than interferon alfa (another medicine used in the treatment of cancer) at prolonging patients' survival. Patients were treated with 25 mg Torisel, with interferon alfa or with 15 mg Torisel in combination with interferon alfa. Patients receiving Torisel alone survived 10.9 months on average compared with 7.3 months in those receiving interferon alfa alone. Patients receiving the lower dose of Torisel in combination with interferon alfa survived for a similar time (8.4 months) as those taking interferon alfa alone.

Mantle cell lymphoma

In mantle cell lymphoma, Torisel was found more effective than alternative cancer medicines (such as gemcitabine or fludarabine) in a main study involving 162 patients whose disease had come back after previous treatment or in whom other treatments had not worked. Each patient received one of two doses of Torisel or the most appropriate alternative cancer medicines chosen by the investigator. The main measure of effectiveness was how long patients lived without the disease getting worse. Patients receiving Torisel lived for 4.8 months on average without their disease getting worse compared with 1.9 months in those receiving the alternative treatment.

What are the risks associated with Torisel?

The most common side effects with Torisel (which may affect more than 1 in 5 patients) include infections, pneumonia (infection of the lungs), thrombocytopenia (low blood platelet counts), anaemia (low red blood cell counts), decreased appetite, hyperglycaemia (high blood sugar levels), hypercholesterolaemia (high blood cholesterol levels), dysgeusia (taste disturbances), difficulty breathing, nose bleeds, cough, vomiting, stomatitis (inflammation of the lining of the mouth), diarrhoea, nausea (feeling sick), rash, pruritus (itching), oedema (swelling), tiredness, weakness, fever and mucosal inflammation (inflammation of moist body surfaces).

The most serious side effects of Torisel are allergic (hypersensitivity) reactions, serious reactions that occur during the infusion or soon afterwards, infections, lung disorders including pneumonitis (inflammation of the lungs) and pulmonary embolism (blood clot in the lung), bleeding in the brain, kidney failure, tearing (perforation) of the intestine, complications affecting the healing of wounds, hyperglycaemia (high blood sugar), thrombocytopenia (low levels of platelets), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection) and hyperlipaemia (high blood levels of a type of fat).

For the full list of side effects of Torisel, see the package leaflet.

Torisel must not be used in people who are hypersensitive (allergic) to temsirolimus, to its metabolites (the substances that it is broken down into) including sirolimus (a medicine used to prevent rejection

of transplanted kidneys), to polysorbate 80 or to any of the other ingredients of the medicine. Torisel must not be used in patients with mantle cell lymphoma who have moderate or severe problems with their liver.

Why is Torisel authorised in the EU?

The European Medicines Agency decided that Torisel's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Torisel?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Torisel have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Torisel are continuously monitored. Side effects reported with Torisel are carefully evaluated and any necessary action taken to protect patients.

Other information about Torisel

Torisel received a marketing authorisation valid throughout the EU on 19 November 2007.

Further information on Torisel can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 03-2018.