European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

TORISEL

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is TORISEL?
TORISEL is a concentrate and diluent that are made up into a solution for infusion (drip into a vein). It contains the active substance temsirolimus.

What is TORISEL used for?
TORISEL is used to treat patients with advanced renal cell carcinoma (kidney cancer).
Because the number of patients with renal cell carcinoma is low, the disease is considered 'rare', and TORISEL was designated an 'orphan medicine' (a medicine used in rare diseases) on 6 April 2006.
The medicine can only be obtained with a prescription.

How is TORISEL used?
TORISEL must be given under the supervision of a doctor who has experience in the use of anticancer medicines. The recommended dose is 25 mg given over 30 to 60 minutes once a week. Patients should receive an antihistamine around 30 minutes before each dose of TORISEL. Treatment with TORISEL should continue until the patient does not benefit any more or has unacceptable side effects. Some side effects can be managed by interrupting treatment or reducing the dose.
TORISEL should be used with caution in patients who have severe problems with their kidneys or who have liver problems. It is not recommended for patients with severe liver problems.

How does TORISEL work?
The active substance in TORISEL, temsirolimus, is an anticancer medicine, which acts by blocking a protein called 'mammalian target of rapamycin' (mTOR). In the body, temsirolimus attaches to a protein that is found 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 kidney cancer.

How has TORISEL been studied?
The effects of TORISEL were first tested in experimental models before being studied in humans.
The effectiveness of TORISEL has been studied in one main study involving 626 patients who had advanced renal cell carcinoma and a poor prognosis. The study compared the effects of 25 mg TORISEL given once a week with those of interferon alfa (another anticancer medicine) and with those of the combination of 15 mg TORISEL once a week in combination with interferon alfa. The main measure of effectiveness was how long the patients survived.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu
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What benefit has TORISEL shown during the studies?
Patients receiving TORISEL alone survived for longer than those taking interferon alfa alone. In the main study, the patients receiving TORISEL alone survived for an average of 10.9 months, compared with 7.3 months in those receiving interferon alfa alone. The patients receiving the lower dose of TORISEL in combination with interferon alfa survived for a similar length of time (8.4 months) to those taking interferon alfa alone.

What is the risk associated with TORISEL?
The most common side effects with TORISEL (seen in more than 3 patients in 10) are anaemia (low red blood cell counts), nausea (feeling sick), rash, anorexia (loss of appetite), oedema (swelling) and asthenia (weakness). For the full list of all side effects reported with TORISEL, see the Package Leaflet.
TORISEL should not be used in people who may be 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.

Why has TORISEL been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that TORISEL's benefits are greater than its risks for the first-line treatment of patients with advanced renal cell carcinoma who have at least three of the following prognostic risk factors:

- less than one year from time of initial renal cell carcinoma diagnosis,
- Karnofsky score status of less than 70,
- haemoglobin less than the lower limit of normal,
- corrected calcium of greater than 10 mg/dl,
- lactate dehydrogenase over 1.5 times the upper limit of normal,
- more than one metastatic organ site.

The Committee recommended that TORISEL be given marketing authorisation.

Other information about TORISEL:
The European Commission granted a marketing authorisation valid throughout the European Union for TORISEL to Wyeth Europa Ltd on 19 November 2007.

The record of TORISEL's designation as an orphan medicine is available here.
The full EPAR for TORISEL can be found here.

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