EMA/301690/2023
EMEA/H/C/003897

Lonsurf (*trifluridine / tipiracil*)

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

What is Lonsurf and what is it used for?

Lonsurf is a medicine used to treat adults with colorectal cancer (cancer of the large bowel) and gastric (stomach) cancer that is metastatic (has spread to other parts of the body). It is used in patients who have already been treated with, or who cannot be given, other treatments for their cancer. It can be used in combination with bevacizumab (another cancer medicine) to treat colorectal cancer.

Lonsurf contains the active substances trifluridine and tipiracil.

How is Lonsurf used?

Treatment with Lonsurf should be prescribed by a doctor who is experienced in the use of cancer medicines. The medicine can only be obtained with a prescription.

Lonsurf is available as tablets to be taken twice a day on certain days of each treatment cycle. Treatment with Lonsurf should continue for as long as the patient benefits from it and the side effects are tolerable.

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

How does Lonsurf work?

Lonsurf is a cytotoxic medicine (a medicine that kills cells that are dividing, such as cancer cells). It contains two active substances: trifluridine and tipiracil.

In the body, trifluridine is converted into an active form that is incorporated into DNA, the genetic material of cells. As a result, trifluridine interferes with DNA function and prevents the cells from dividing to make more cells.

The conversion of trifluridine into its active form occurs more readily in cancer cells than in normal cells, leading to higher levels of the active form of the medicine and a longer duration of action in cancer cells. This reduces the growth of cancer cells, while normal cells are only slightly affected.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union

Tipiracil increases the level of trifluridine in the blood by slowing its breakdown. This boosts trifluridine's effect.

What benefits of Lonsurf have been shown in studies?

Lonsurf prolonged overall survival (how long patients lived after starting treatment) in patients with metastatic colorectal cancer and in patients with metastatic gastric cancer. All patients in the studies had previously received other treatments.

Colorectal cancer

In one main study involving 800 patients, those treated with Lonsurf lived on average for 7.1 months, compared with 5.3 months for patients who were given placebo (a dummy treatment). All patients received supportive care.

In a second main study involving 492 patients, those treated with Lonsurf and bevacizumab lived on average for 10.8 months, compared with 7.5 months for patients who were given only Lonsurf.

Gastric cancer

In a study involving 507 adults with metastatic gastric cancer, patients treated with Lonsurf lived on average for 5.7 months, compared with 3.6 months for patients who received placebo. All patients received supportive care.

What are the risks associated with Lonsurf?

For the full list of side effects and restrictions of Lonsurf, see the package leaflet.

When used on its own, the most common side effects with Lonsurf (which may affect more than 3 in 10 people) include neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), nausea (feeling sick), tiredness and anaemia (low levels of red blood cells).

When used in combination with bevacizumab, the most common side effects with Lonsurf (which may affect more than 3 in 10 people) include neutropenia, tiredness and nausea.

Why is Lonsurf authorised in the EU?

The European Medicines Agency decided that Lonsurf's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that the benefit of Lonsurf in prolonging survival in patients with metastatic colorectal and metastatic gastric cancer who have received previous treatment was important.

Regarding its safety, although Lonsurf's side effects can be serious, they are in line with what can be expected for this type of medicine. The Agency considered that the measures put in place are adequate to manage these risks.

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

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

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

Other information about Lonsurf

Lonsurf received a marketing authorisation valid throughout the European Union on 25 April 2016.

Further information on Lonsurf can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lonsurf.

This overview was last updated in 07-2023.