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EPAR summary for the public

Lonsurf

trifluridine/tipiracil

This is a summary of the European public assessment report (EPAR) for Lonsurf. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lonsurf.

For practical information about using Lonsurf, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lonsurf and what is it used for?

Lonsurf is a cancer medicine used to treat adults with metastatic colorectal cancer (cancer of the large bowel that 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 available treatments including chemotherapy based on medicines called fluoropyrimidines, oxaliplatin or irinotecan and treatment with other cancer medicines known as anti-VEGF and anti-EGFR.

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 (15 mg trifluridine and 6.14 mg tipiracil; 20 mg trifluridine and 8.19 mg tipiracil) and is given in treatment cycles of 28 days. The dose to be taken is calculated based on the patient's body surface area (calculated using the patient's height and weight). The tablets are taken twice a day on days 1 to 5 and days 8 to 12 of each treatment cycle. They should be taken within one hour after morning and evening meals. The doctor may need to reduce the dose or interrupt treatment

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

if certain side effects develop. Treatment with Lonsurf should continue for as long as benefits can be seen and the side effects are tolerable.

For further information, see the summary of product characteristics (also part of the EPAR).

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 directly into DNA, the genetic material of cells. As a result, trifluridine interferes with DNA function and prevents the cells from dividing and multiplying.

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 results in the growth of cancer cells being reduced, while normal cells are only slightly affected.

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

What benefits of Lonsurf have been shown in studies?

Lonsurf has been shown to prolong overall survival of patients with metastatic colorectal cancer who previously received other treatments. 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 treated with placebo (a dummy treatment). All patients in the study received supportive care.

What are the risks associated with Lonsurf?

The most common side effects with Lonsurf (which may affect more than 3 in 10 people) are neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), nausea, tiredness, anaemia (low red blood cell counts) and leucopenia (low white blood cell counts). The most serious side effects are bone marrow suppression (when the bone marrow produces less blood cells than normal) and gastrointestinal toxicity (injury to the lining of the gut such as ulcers).

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

Why is Lonsurf approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Lonsurf's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that the benefit of Lonsurf in prolonging survival in patients with metastatic colorectal cancer who have received previous treatment was clinically relevant.

Regarding its safety, although Lonsurf's side effects can be serious they are in line with what can be expected for a cytotoxic medicine. The CHMP 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?

A risk management plan has been developed to ensure that Lonsurf is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Lonsurf, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Lonsurf

The European Commission granted a marketing authorisation valid throughout the European Union for Lonsurf on 25 April 2016.

The full EPAR for Lonsurf can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Lonsurf, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2016.