

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

PrLONSURF®
trifluridine and tipiracil tablets

Read this carefully before you start taking **Lonsurf** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Lonsurf**.

Serious Warnings and Precautions

Lonsurf should only be prescribed by a doctor with experience in the use of anti-cancer drugs.

The following serious side effects have been seen in people taking Lonsurf:

- **Bone Marrow Suppression (Myelosuppression):** signs and symptoms of infections (including fever, chills, sore throat, mouth ulcers), fatigue, easy bruising, bleeding of the nose, gums or mouth, tiny red spots on the skin, rash, shortness of breath, pale skin lips and nail beds.
- **Stomach Problems (Gastrointestinal Toxicity):** nausea, vomiting and diarrhea that can cause you to become dehydrated.

What is Lonsurf used for?

Lonsurf is a drug used to treat adults with some types of cancer that have spread to other parts of the body. These cancers are:

- Colon or rectal cancer
 - Lonsurf is used when other treatments have not worked or when other treatments are not suitable for you.
- A type of stomach cancer called gastric cancer or a type of esophageal cancer called gastroesophageal junction cancer.
 - Lonsurf is used after at least two other treatments.

How does Lonsurf work?

Lonsurf has two drugs: trifluridine and tipiracil. The two drugs may help stop cancer from growing.

What are the ingredients in Lonsurf?

Medicinal ingredients: trifluridine and tipiracil (as tipiracil hydrochloride)

Non-medicinal ingredients: carnauba wax, FD&C Blue No. 2 Aluminum Lake, ferric oxide red, ferric oxide yellow, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, pregelatinized starch, shellac, stearic acid, talc and titanium dioxide.

Lonsurf comes in the following dosage forms:

Tablets: 15 mg/6.14 mg and 20 mg/8.19 mg

Do not use Lonsurf if you:

- are allergic to trifluridine or tipiracil or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Lonsurf. Talk about any health conditions or problems you may have, including if you:

- have or have a history of kidney disease
- have or have a history of liver disease
- have had radiation treatment for your cancer
- are pregnant or you or your partner are planning on becoming pregnant
- are breastfeeding or planning to breastfeed. You should not breastfeed while taking Lonsurf and for one day after your last dose.
- have an intolerance to lactose
- are 65 years of age or older as you may be at higher risk of side effects related to low blood cell levels.

Other warnings you should know about:

Pregnancy and Contraception

Lonsurf can harm your unborn baby. You should not become pregnant or father a child while you are taking Lonsurf. If you are a female who could become pregnant or if you are a male taking Lonsurf and your female partner could become pregnant, you must use a very effective birth control while taking Lonsurf, and for 6 months after your last dose. It is not known if Lonsurf reduces the effectiveness of hormonal birth control (such as “the pill”), therefore women using hormonal birth control should also use a barrier birth control such as condoms. If you think you, or your female partner, have become pregnant contact your healthcare professional immediately.

Serious Side Effects

Tell your healthcare professional immediately if you experience any of the following as they could be signs of very serious side effects:

- signs of infection such as sore throat, mouth ulcers or a fever - these may be signs of low white blood cells
- feeling short of breath, tired or having pale skin - these may be signs of low red blood cells (anemia)
- unusual bruising or bleeding - these may be signs of low blood cells platelets
- stomach problems such as feeling sick (nausea) or being sick (vomiting) or having diarrhea - you may be at risk of dehydration

Driving and Operating Machinery

If you experience symptoms such as fatigue, dizziness or generally feeling unwell, which affects your ability to concentrate and react, while taking Lonsurf you should not drive or use machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Lonsurf:

- Take Lonsurf twice daily. In the morning within 1 hour of eating your morning meal and in the evening within 1 hour of eating your evening meal.

- Take exactly as directed by your healthcare professional. Check with your doctor, pharmacist or nurse if you are not sure.
- Lonsurf must be taken with a glass of water. Swallow Lonsurf tablets whole. Take Lonsurf on Days 1 to 5 and again on Days 8 to 12 of a 28-day treatment cycle. Each treatment cycle is repeated every 4 weeks.
- Lonsurf must be handled with caution. Always wash your hands after handling Lonsurf tablets.

Usual adult dose:

Your doctor will determine the right dose for you. Your dose will depend on your weight and height and if you have severe kidney problems. Your healthcare professional will tell you how many tablets to take.

Lonsurf comes in two strengths. Your doctor may prescribe one or both strengths for your prescribed dose.

Your doctor may interrupt or reduce your dose or tell you to stop taking Lonsurf. This may happen if you have certain side effects.

Overdose:

If you think you have taken too much Lonsurf, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Do not take additional doses of Lonsurf to make up for missed or held doses.

What are the possible side effects from using Lonsurf?

These are not all the possible side effects you may feel when taking Lonsurf. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Weakness
- Feeling tired
- Decreased appetite
- Abdominal pain
- Indigestion
- Common cold
- Hair loss
- Swelling of the gums, tongue, lips and/or mouth
- Rash
- Bleeding gums
- Change in taste

Regular blood and urine tests are important while taking Lonsurf. This includes blood tests before you start treatment with Lonsurf and before each new treatment cycle. Your healthcare professional will decide when to perform blood and urine tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Stomach problems (Gastrointestinal toxicity): nausea, vomiting and diarrhea which may lead to dehydration		√	
RARE			
Bone marrow suppression (Myelosuppression): unusual bruising or bleeding, feeling short of breath, tired or having pale skin or signs of infection (fever, chills, sore throat, mouth ulcers)		√	
Pulmonary embolism: shortness of breath, severe chest pain, coughing up blood			√
Lung problems (interstitial lung disease, pneumonitis): fatal and serious or with suddenly worsening of shortness of breath, wheezing, tiredness, possibly with a cough or fever, painful breathing have been reported in Asian (especially Japanese) patients.			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Lonsurf should be stored at room temperature (15°C to 30°C).

Hands should be washed after handling Lonsurf tablets.

Keep out of reach and sight of children.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

If you want more information about Lonsurf:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); www.taihopharma.ca, or by calling 1-844-648-2446.

This leaflet was prepared by Taiho Pharma Canada, Inc.
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