

PATIENT INFORMATION
LONSURF® (LON-serf)
(trifluridine and tipiracil)
tablets

What is the most important information I should know about LONSURF?

Your healthcare provider should do blood tests before you receive LONSURF, at day 15 during treatment with LONSURF, and as needed to check your blood cell counts.

LONSURF may cause serious side effects, including:

Low blood cell counts. Low blood counts are common with LONSURF and can sometimes be severe and life-threatening. LONSURF can cause a decrease in your white blood cells, red blood cells, and platelets. Low white blood cells can make you more likely to get serious infections that could lead to death. Your healthcare provider may:

- lower your dose of LONSURF or stop LONSURF if you have low white blood cell or low platelet counts.

Tell your healthcare provider right away if you get any of the following signs and symptoms of infection during treatment with LONSURF:

- fever
- chills
- body aches

See “**What are the possible side effects of LONSURF?**” for more information about side effects.

What is LONSURF?

LONSURF is a prescription medicine used:

- alone or in combination with the medicine bevacizumab to treat adults with colorectal cancer:
 - that has spread to other parts of the body, **and**
 - who have been previously treated with certain chemotherapy medicines.
- alone to treat adults with a kind of stomach cancer called gastric cancer including adenocarcinoma of the gastroesophageal junction:
 - that has spread to other parts of the body, **and**
 - who have been previously treated with at least 2 types of treatment which included certain medicines.

It is not known if LONSURF is safe and effective in children.

Before you take LONSURF, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney or liver problems
- are pregnant or plan to become pregnant. LONSURF can harm your unborn baby.

For females who can become pregnant:

- Your healthcare provider will do a pregnancy test before you start treatment with LONSURF.
- You should use effective birth control during treatment with LONSURF and for at least 6 months after your last dose of LONSURF. (Talk to healthcare provider about methods of birth control that can be used during this time)
- Tell your healthcare provider right away if you become pregnant.

For males:

- You should use a condom during sex with female partners who are able to become pregnant during your treatment with LONSURF and for 3 months after your last dose of LONSURF. Tell your healthcare provider right away if your partner becomes pregnant while you are taking LONSURF.
- are breastfeeding or plan to breastfeed. It is not known if LONSURF passes into breast milk. Do not breastfeed during treatment with LONSURF and for 1 day after your last dose of LONSURF.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I take LONSURF?

- Take LONSURF exactly as your healthcare provider tells you. LONSURF comes in two strengths. Your healthcare provider may prescribe both strengths for your prescribed dose.
- Take LONSURF 2 times a day with food.
- Swallow LONSURF tablets whole.
- Your caregiver should wear gloves when handling LONSURF tablets.

- If you vomit right after taking a dose, or miss a dose of LONSURF, do not take additional doses to make up for the vomited or missed dose. Call your healthcare provider for instructions about what to do for a missed dose.
- Wash your hands after handling the LONSURF tablets.

What are the possible side effects of LONSURF?

LONSURF may cause serious side effects, including:

- See “**What is the most important information I should know about LONSURF?**”

The most common side effects of LONSURF when used alone include:

- low blood counts
- tiredness and weakness
- nausea
- decreased appetite
- diarrhea
- vomiting
- stomach-area (abdominal) pain
- fever

The most common side effects of LONSURF when used in combination with bevacizumab include:

- low blood counts
- tiredness and weakness
- nausea
- certain abnormal liver function blood tests
- decreased salt (sodium) in your blood
- diarrhea
- stomach-area (abdominal) pain
- decreased appetite

Tell your healthcare provider if you have nausea, vomiting, or diarrhea that is severe or that does not go away. These are not all of the possible side effects of LONSURF. For more information, ask your healthcare provider. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LONSURF?

- Store LONSURF at room temperature between 68°F and 77°F (20°C and 25°C).
- If you store LONSURF outside of the original bottle, throw away (dispose of) any unused LONSURF tablets after 30 days.
- Talk to your healthcare provider about how to safely dispose of LONSURF.

Keep LONSURF and all medicines out of the reach of children.

General information about the safe and effective use of LONSURF

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LONSURF for a condition for which it was not prescribed. Do not give LONSURF to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about LONSURF that is written for health professionals.

What are the ingredients in LONSURF?

Active ingredients: trifluridine and tipiracil hydrochloride

Other ingredients: lactose monohydrate, pregelatinized starch, stearic acid, hypromellose, polyethylene glycol, titanium dioxide, ferric oxide, and magnesium stearate

Imprinting ink: shellac, ferric oxide red, ferric oxide yellow, titanium dioxide, FD&C Blue No. 2 Aluminum Lake, carnauba wax, and talc.

Manufactured by: Taiho Pharmaceutical Co., Ltd., Japan

Manufactured for: Taiho Oncology, Inc., Princeton, NJ 08540 USA

LONSURF is a registered trademark of Taiho Pharmaceutical Co., Ltd. used under license by Taiho Oncology, Inc.

For more information, go to www.Lonsurf.com or call 1-844-878-2446.