

PATIENT INFORMATION
LONSURF® (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 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 to treat people with colon or rectal cancer that has spread to other parts of the body and who have been previously treated or cannot receive certain chemotherapy 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:

- You should use effective birth control during treatment with LONSURF.
- 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 one 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 within 1 hour after eating your morning or evening meals.
- Your caregiver should wear gloves when handling LONSURF tablets.
- If you miss a dose of LONSURF, do not take additional doses to make up for the 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 include:

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| • tiredness | • vomiting |
| • nausea | • abdominal pain |
| • decreased appetite | • fever |
| • diarrhea | |

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 (20 mg tablet only), 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 Oncology, Inc. For more information, go to www.Lonsurf.com or call 1-844-878-2446.

This Patient Information has been approved by the U.S. Food and Drug Administration

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