BECAUSE TOMORROW IS STILL UNWRITTEN

Help your loved one continue their story with LONSURF® (trifluridine/tipiracil) [LON-serf] tablets

LONSURF is a prescription medicine used to treat adults with

- colorectal cancer that has spread to other parts of the body and who have been previously treated or cannot receive certain chemotherapy medicines.
- a kind of stomach cancer called gastric cancer including cancer of the gastroesophageal junction that has spread to other parts of the body and who have been previously treated or cannot receive certain chemotherapy medications.

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

Please see Important Safety Information on pages 22-23 and full Prescribing Information in pocket.





A GUIDE FOR CAREGIVERS

INTRODUCTION

About this guide

You and your loved one have been through a lot. You have seen rounds of treatments, side effects, and a whole new way of living. What is normal keeps changing and priorities change, too. It is important to recognize this shift. It is also important to support the way your loved one chooses to manage the next part of his or her journey.

This brochure is meant to help you understand:

- Your loved one's treatment with LONSURF® (trifluridine/tipiracil) tablets
- How to help your loved one with his or her treatment plan
- That it is important for you to take care of yourself, too

Inside, you will find information about:

- Two different cancers: colon/rectal cancer and stomach cancer
- Your loved one's cancer
- The caregiver
- Treatment with LONSURF (who it is for and how it works)
- How LONSURF is taken
- Side effects and how to help manage them

You will also find answers to some frequently asked questions about LONSURF, Important Safety Information, and places to find additional support.



The role of the caregiver

A caregiver provides more than just care for a patient. A caregiver is many things:

- An advocate
- A friend
- An extra set of hands
- A trusted comfort and guide along the treatment journey

Here are some things you may already do, but are good to keep in mind about the caregiver role:

- Educate yourself and stay informed about your loved one's treatment plan and schedule
- Organize an emergency contact list and a folder for important health resources
- Know your loved one's limits
- Go to check-ups with your loved one. He or she may not make sense of what the healthcare provider says. Listen closely so you can explain later
- Be honest and clear



Listening to your loved one is just as important as talking to him or her.

Take what he or she says to heart. You do not need to have all the answers.

Simply being an active listener can help your loved one find answers and feel heard.



Caring for yourself

You play a key part in your loved one's treatment journey, but you are not alone. There are family members, doctors, nurses, an extended care team, and other resources to help you and your loved one through this.

Being a caregiver is not easy. Cancer makes a big impact not only on the patient, but also on those around him or her. It can take an emotional and physical toll. Sometimes, it is easy to forget about yourself. Your well-being has a direct effect on how well you care for your loved one.

It is important to maintain balance in your life. Find a little part of your day to relax and take care of yourself. Take some time to participate in things you enjoy. Plan time for:

- Mental health: Have coffee with a friend or dinner with your wife, husband, or partner; watch a movie, read a book, or listen to music
- Physical health: Get regular exercise, go for a walk, stretch, do yoga, continue with any sports or clubs you are part of. Remember that a few minutes every day can still make a difference
- Emotional/spiritual health: Consider meditation, stay in touch with your religious community and/or social support networks, and try to appreciate the good things and people in your life

Getting the support you need

You don't have to take on the entire task of providing care. Don't be afraid to ask for help. Create a support network. This could be close family or friends. Plan a schedule for the week and share it with family and friends so they can help. The doctor, nurses, or office staff may help you find a counselor, support group, or other means of support.

Selected Important Safety Information

• 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 should do blood tests before you receive LONSURF, at day 15 during treatment with LONSURF, and as needed to check your blood cell counts. Your healthcare provider may lower your dose of LONSURF or stop LONSURF if you have low white blood cell or platelet counts



ABOUT COLON OR RECTAL CANCER

About metastatic colon or rectal cancer (mCRC)

- It is the third most common cancer in men and women
- In the US, approximately 1 in 22 men and 1 in 24 women will be diagnosed with colon or rectal cancer in his or her lifetime
- In 2017, the estimated number of people diagnosed with colon or rectal cancer in the United States was projected to be about:
 - 71,400 men
 - 64,000 women
- Combined, colon and rectal cancer make up the third leading cause of cancer-related death in both men and women in the United States. However, death rates have been dropping, especially in the last 10 years. The declines are thought to be due in part to:
 - Increased screening
 - Improved treatment

Metastatic means that the cancer has spread to other parts of the body.

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Stay informed and get support

The following organizations can provide you with mCRC resources, advocacy, community, and support:

CancerCare®

Visit cancercare.org or call 1-800-813-HOPE (4673)

Cancer Support Community®

Visit cancersupportcommunity.org or call 1-888-793-9355

Colontown®

Visit colontown.org or call 1-410-881-3160

Colorectal Cancer Alliance

Visit ccalliance.org or call 1-877-422-2030

Fight Colorectal Cancer®

Visit fightcolorectalcancer.org or call 1-877-427-2111

The Raymond Foundation

Visit TheRaymondFoundation.org or call 1-646-598-2001

Selected Important Safety Information

Tell your healthcare provider right away if you get any of the following signs and symptoms of infection during treatment with LONSURF: fever, chills, or body aches.



ABOUT STOMACH CANCER

About metastatic stomach cancer

- Metastatic stomach cancer is not as common as some other cancers
- In 2016, there were an estimated 113,054 people living with stomach cancer in the United States
- In 2019:
 - An estimated 27,510 people were diagnosed with stomach cancer
 - Stomach cancer was 1.6% of all new cancer cases in the United States
- Approximately 0.9% of men and women will be diagnosed with stomach cancer at some point during their lifetime
- Gastroesophageal junction cancer, a type of stomach cancer, is reportedly the fastest rising cancer diagnosis

Metastatic means that the cancer has spread to other parts of the body.

Stomach cancer is sometimes called gastric cancer.

Your healthcare provider may have told your loved one that he
or she has gastroesophageal junction cancer, which is a type of
stomach cancer located in the lower part of the esophagus that
connects to the stomach

Trademarks, registered or otherwise, are the property of their respective owners.

Stay informed and get support

The following organizations can provide you with stomach cancer resources, advocacy, community, and support:

CancerCare®

Visit cancercare.org or call 1-800-813-HOPE (4673)

Cancer Support Community®

Visit cancersupportcommunity.org or call 1-888-793-9355

Debbie's Dream Foundation

Visit debbiesdream.org or call 1-855-475-1200

Gastric Cancer Foundation

Visit gastriccancer.org

Hope for Stomach Cancer

Visit stocan.org or call 1-424-239-9943

No Stomach For Cancer®

Visit nostomachforcancer.org or call 1-608-692-5141

The Raymond Foundation

Visit TheRaymondFoundation.org or call 1-646-598-2001

Selected Important Safety Information

Before taking 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.



Treatment with LONSURF

LONSURF® (trifluridine/tipiracil) tablets, a prescription medicine, are for people:

- Whose colon/rectal or stomach cancer has spread to other parts of the body
- Who have been previously treated with or cannot receive certain chemotherapy medicines
- Who now may need another option

LONSURF has been proven to help some patients with cancer live longer. LONSURF consists of 2 medicines in 1:

 One part (tipiracil) helps the other part (trifluridine) stay active and work properly, and stops cells from making copies of themselves. This may help stop tumors from growing

LONSURF was studied in a clinical trial of 800 patients with **colon or rectal cancer** that had spread to other parts of the body and had been previously treated with certain chemotherapy medicines.

- Half of the patients treated with LONSURF were still alive at 7.1 months and half of the patients who received placebo were still alive at 5.3 months
- Worsening of the disease or death occurred in 88% of patients treated with LONSURF and 94% of patients who received placebo

LONSURF was studied in a clinical trial of 507 patients with **stomach cancer** that had spread to other parts of the body and had been previously treated with certain chemotherapy medicines.

- Half of the patients treated with LONSURF were still alive at 5.7 months and half of the patients who received placebo were still alive at 3.6 months
- Worsening of the disease or death occurred in 85% of patients treated with LONSURF and 92% of patients who received placebo

How to take LONSURF

LONSURF is an oral tablet and comes in 2 strengths: 15-mg and 20-mg tablets.* The healthcare provider may prescribe both strengths for your loved one's prescribed dose.



15-mg tablet



20-mg tablet

Tablets shown at actual size

Help make sure your loved one is taking LONSURF:

- Twice a day with food
- The type of food does not matter

Selected Important Safety Information

- **Females** who can become pregnant: Your healthcare provider will verify your pregnancy status before you start treatment with Lonsurf. You should use effective birth control during and 6 months after the last dose of treatment with LONSURF. Tell your healthcare provider immediately if you become pregnant
- Males, while on treatment and for 3 months after your last dose of LONSURF, you should use a condom during sex with female partners who are able to become pregnant. Tell your healthcare provider right away if your partner becomes pregnant while you are taking LONSURF
- Are breast-feeding or plan to breast-feed. It is not known if LONSURF passes into your breast milk. Do not breast-feed during treatment with LONSURF and for 1 day after your last dose of LONSURF



^{*}Tablet strength of LONSURF is based on 1 active part of the medicine. Actual tablet size is 7 mm for 15-mg dose and 8 mm for 20-mg dose.

Tips for the LONSURF 28-day dosing schedule



First daily dose



Second daily dose

Day 1:	Day 2:	Day 3:	Day 4:	Day 5:	Day 6: REST	Day 7: REST
1st dose 2nd dose	1st 2nd dose	1st 2nd dose	1st 2nd dose	1st 2nd dose		
Day 8:	Day 9:	Day 10:	Day 11:	Day 12:	Day 13: REST	Day 14: REST
1st 2nd dose	1st 2nd dose	1st 2nd dose	1st 2nd dose	1st 2nd dose		
Day 15: REST	Day 16: REST	Day 17: REST	Day 18: REST	Day 19: REST	Day 20: REST	Day 21: REST
Day 22: REST	Day 23: REST	Day 24: REST	Day 25: REST	Day 26: REST	Day 27: REST	Day 28: REST

The dosing schedule for LONSURF® (trifluridine/tipiracil) tablets is 5 days a week with 2 days rest for 2 weeks, then no treatment for 2 weeks (14 days). The cycle may be repeated. Always follow the healthcare provider's directions carefully.

Use the digital calendar at **LONSURF.com/mycalendar** to help you keep track of your loved one's treatment. The healthcare provider may give you a treatment calendar as well.

Other things to keep in mind about treatment with LONSURF

- Store LONSURF at room temperature between 68°F and 77°F (20°C and 25°C)
- Don't store LONSURF with other medicines. Keep LONSURF in its own container
- If you store the tablets outside of the original container, any unused LONSURF tablets should be disposed of after 30 days
- Make sure you wear gloves when handling LONSURF
- Wash your hands after handling LONSURF. Even though it is a pill, it is still chemotherapy
- Note that there is a packet inside the bottle that helps absorb moisture.
 Be sure your loved one doesn't swallow this material
- Keep LONSURF out of the reach of children

Contact your loved one's healthcare provider:

- If your loved one misses a dose of LONSURF, he or she should not take the missed dose. Instead, check with a healthcare provider about how to proceed
- If for some reason your loved one has leftover tablets, you should speak with a healthcare provider or pharmacist about how to dispose of them properly

Selected Important Safety Information

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

The **most common side effects** with LONSURF include tiredness (fatigue, weakness), nausea, decreased appetite, diarrhea, vomiting, abdominal pain, and fever.



Side effects

It's important to know what to expect so you can recognize side effects right away and talk with the healthcare provider. There are things you can do to help your loved one manage the effects, while the treatment team is monitoring their symptoms.

A healthcare provider should check your loved one's blood cell counts before he or she receives LONSURF® (trifluridine/tipiracil) tablets, at day 15 during treatment, and as needed.

- Low blood cell counts are common with LONSURF and can sometimes be severe and life-threatening. LONSURF can cause a decrease in white blood cells, red blood cells, and platelets. Low white blood cells can make your loved one more likely to get serious infections that could lead to death.
 A healthcare provider may lower the dose of LONSURF or stop LONSURF if your loved one has low white blood cell or low platelet counts
- Tell a healthcare provider right away if your loved one develops any signs of infection such as fever, chills, or body aches

Fever is often the first sign of infection in people with cancer. You can use the thermometer provided in the Starter Kit to check your loved one's temperature each day.

Keep an eye out for other signs of infection, like:

- Chills or sweats
- Sore throat

- Cough or shortness of breath
- Burning or pain when urinating

Things to do to help avoid infection:

- Wash hands frequently
- Maintain a balanced diet
- Stay hydrated
- Clean cuts and scrapes in the skin
- Clean the anus with moist towelettes or baby wipes after bowel movements
- Get plenty of sleep

The most common side effects

Almost all patients treated with LONSURF experience side effects at some time.

The most common side effects of LONSURF include:

- Tiredness (fatigue/weakness)
- Nausea
- Vomiting
- Decreased appetite

- Diarrhea
- Abdominal pain
- Fever



Talk to your loved one's healthcare provider if he or she has nausea, vomiting, or diarrhea that is severe or that does not go away.

These are not all of the possible side effects of LONSURF.

You can also call the Taiho Oncology 24/7 hotline with questions about side effects with LONSURF at **1-844-US-TAIHO** (**1-844-878-2446**). You may report side effects to the FDA at **1-800-FDA-1088**.



Tips for managing side effects

Your loved one's healthcare provider may have ways to help manage some of the side effects of LONSURF® (trifluridine/tipiracil) tablets. This could include adjusting your loved one's treatment plan by changing the dosage or stopping treatment.

The following information may also be helpful to you or your loved one in managing some of the side effects of LONSURF while under a healthcare provider's care.



This information is not meant to replace the advice of your loved one's healthcare provider. Always discuss any side effects with a healthcare provider. If your loved one has stomach cancer, speak to their healthcare provider for special dietary needs that may be impacted by their condition before managing any effects on appetite.



Tiredness (fatigue/weakness)

Help your loved one:

- Set reasonable goals each day and don't let them overdo it
- Prioritize important tasks over less important ones. Plan time to rest or nap (less than 1 hour). Keeping naps short will help with better sleep at night
- Stay active. Talk with a healthcare provider about exercise that can help,

- like going for a 15-minute walk, doing yoga, or riding an exercise bike
- Get at least 8 hours of sleep each night
- Establish a bedtime routine. Bathing or listening to relaxing music before bed may help

Nausea and vomiting

Remind your loved one to:

- Make 5 or 6 small meals a day, instead of 3 big ones (this does not change the dosing schedule)
- Have food and drinks that are warm or cool instead of hot or cold
- Choose foods that are easy on the stomach, like saltine crackers or angel food cake

- Avoid certain foods. Don't eat greasy, fried, sweet, or spicy foods if you feel sick after eating them
- Take any medicine a healthcare provider prescribes to help with nausea





Decreased appetite

Remind your loved one to:

- Make 5 or 6 small meals a day, instead of 3 big ones (this does not change the dosing schedule)
- Have milkshakes, smoothies, juice, or soup instead of solid food
- Choose foods that are high in calories and/or protein
- Stay active. Talk with a healthcare provider about exercises that can help, like going for a 15-minute walk

- Plan some meals with friends and loved ones
- Ask a healthcare provider about seasonings that may help some foods taste better
- Take note of how much he or she is eating and drinking each day
- Speak to the healthcare provider if your loved one has stomach cancer for special dietary needs that may be impacted by their condition

Diarrhea/abdominal pain

For diarrhea, encourage your loved one to:

- Make 5 or 6 small meals a day, instead of 3 big ones (this does not change the dosing schedule)
- Eat low-fiber foods. Foods that are high in fiber can make diarrhea worse. Low-fiber foods include bananas, white rice, white toast, and plain or vanilla yogurt
- Eat bland foods instead of greasy, fried, salty, sweet, or spicy foods
- Avoid dairy products such as milk, cheese, and sour cream

- Avoid alcohol and caffeine
- Drink plenty of liquids to replace the fluids being lost
- Use warm water and a towelette if the rectal area becomes sore, and keep the area dry. Also, ask a healthcare provider about creams that can help
- Take any medicine that a healthcare provider prescribes to help with diarrhea

For abdominal pain, encourage your loved one to:

- Eat plenty of foods that are high in fiber such as fruits and vegetables
- Exercise regularly

Avoid foods that produce gas



Fever

Remind your loved one to:

- Drink plenty of liquids, like water, juice, and soup, because a fever can cause fluid loss and dehydration
- Get rest
- Keep cool by dressing in light clothing and sleeping with only a sheet
- Call a healthcare provider immediately if he or she has a fever or other signs of infection such as chills or body aches. Your loved one can use the thermometer provided in the Starter Kit to check his or her temperature each day



Tell your loved one's healthcare provider if he or she has nausea, vomiting, or diarrhea that is severe or that does not go away.

You or your loved one can also use the digital LONSURF Treatment Calendar at **LONSURF.com/mycalendar** to track any side effects or other issues for discussion with a healthcare provider at their next appointment.



Selected Important Safety Information

Tell your doctor 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.



Important Safety Information

LONSURF® (trifluridine/tipiracil) tablets 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 should do blood tests before you receive LONSURF, at day 15 during treatment with LONSURF, and as needed to check your blood cell counts. Your healthcare provider may lower your dose of LONSURF or stop LONSURF if you have low white blood cell or 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, or body aches.

Before taking 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.
- **Females** who can become pregnant: Your healthcare provider will verify your pregnancy status before you start treatment with Lonsurf. You should use effective birth control during and 6 months after the last dose of treatment with LONSURF. Tell your healthcare provider immediately if you become pregnant
- Males, while on treatment and for 3 months after your last dose of LONSURF, you should use a condom during sex with female partners who are able to become pregnant. Tell your healthcare provider right away if your partner becomes pregnant while you are taking LONSURF

 Are breast-feeding or plan to breast-feed. It is not known if LONSURF passes into your breast milk. Do not breast-feed during treatment with LONSURF and for 1 day after your last dose of LONSURF

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

The **most common side effects** with LONSURF include tiredness (fatigue, weakness), nausea, decreased appetite, diarrhea, vomiting, abdominal pain, and fever.

Tell your doctor 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.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 02/2019



Frequently asked questions

How do LONSURF® (trifluridine/tipiracil) tablets work against colon/rectal cancer and stomach cancer?

LONSURF is an oral chemotherapy that is 2 medicines in 1. It interferes with cell replication in the life cycle of cells.

- One part helps the other part stay active and work properly
- The other part stops cells from making copies of themselves. This may help stop tumors from growing

What if my loved one or I have a question about LONSURF and the healthcare provider's office is not available?

Contact our 24-hour call center, where you can get answers to your questions about LONSURF, at **1-844-US-TAIHO** (1-844-878-2446), or visit **LONSURF.com/caregivers**.

Where can I get help understanding what costs will be associated with LONSURF treatment and find out about financial assistance?

Taiho Oncology Patient Assistance provides:

- Help with understanding your loved one's insurance coverage and what payments he or she will be responsible for
- Co-pay assistance at TaihoOncologyCopay.com
- Financial assistance for uninsured or underinsured patients who qualify

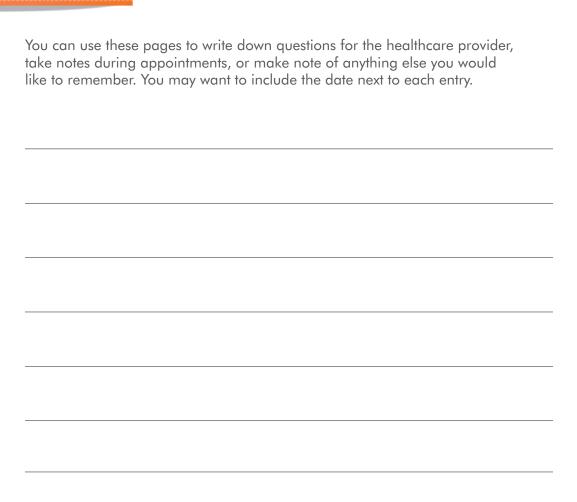
For more information about Taiho Oncology Patient Assistance:

- Call 1-844-TAIHO-4U (1-844-824-4648) Monday-Friday, 8 AM to 8 PM ET
- Go to TaihoPatientSupport.com
- See the Patient Access Brochure available at LONSURF.com/resources





NOTES













Taiho Oncology is committed to providing ongoing services that include treatment support, referral to financial assistance resources to help pay for your loved one's medicine, informational e-mails, and access to our call center, where you can get answers to your questions about LONSURF® (trifluridine/tipiracil) tablets.

For more support with LONSURF:

- Call 1-844-TAIHO-4U (1-844-824-4648) Monday-Friday, 8 AM to 8 PM ET
- Go to TaihoPatientSupport.com
- See the Patient Access Brochure available at LONSURF.com/resources

Please see Important Safety Information on pages 22-23 and full Prescribing Information in pocket.

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