

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LONSURF?

LONSURF is a medicine used to treat cancer by slowing down the growth and spread of cancer cells. LONSURF contains two different active substances trifluridine and tipiracil. Trifluridine stops the growth of cancer cells. Tipiracil stops the trifluridine from being broken down by the body, helping trifluridine to work longer.

For more information, see Section [1. Why am I using LONSURF?](#) in the full CMI.

2. What should I know before I use LONSURF?

Do not use if you have ever had an allergic reaction to LONSURF or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LONSURF?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LONSURF and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LONSURF?

Your doctor will usually prescribe LONSURF for 10 days during the first two weeks and then stop for two weeks.

This two week on, two weeks off treatment period is one 'cycle' of treatment.

You will then begin another treatment cycle following the above pattern.

The specific dosing schedule is outlined in the full CMI.

More instructions can be found in Section [4. How do I use LONSURF?](#) in the full CMI.

5. What should I know while using LONSURF?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist, nurse or pharmacist you visit that you are using LONSURF.• Tell your doctor immediately if you become pregnant during treatment with LONSURF, or plan to become pregnant.• Tell your doctor if you are breast-feeding while being treated with LONSURF.• If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests. |
| Things you should not do | <ul style="list-style-type: none">• Do not take LONSURF to treat any other complaints unless your doctor tells you to.• Do not stop taking LONSURF, or lower the dosage, even if you are feeling better, without checking with your doctor. |
| Driving or using machines | <ul style="list-style-type: none">• Do not drive or operate machinery until you know how LONSURF affects you. Speak with your doctor about when you can resume these activities. |
| Looking after your medicine | <ul style="list-style-type: none">• Store in a cool dry place away from moisture, heat and sunlight. Keep out of reach of children.• Keep your tablets in the pack until it is time to take them. |

For more information, see Section [5. What should I know while using LONSURF?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking LONSURF. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

If you experience neutropenia, anaemia, vomiting and diarrhoea, thrombocytopenia, febrile neutropenia or abdominal pain after taking LONSURF, **please seek urgent medical attention.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

LONSURF®

Active ingredient(s): trifluridine and tipiracil

Consumer Medicine Information (CMI)

This leaflet provides important information about using LONSURF. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LONSURF.**

Where to find information in this leaflet:

- [1. Why am I using LONSURF?](#)
- [2. What should I know before I use LONSURF?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LONSURF?](#)
- [5. What should I know while using LONSURF?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using LONSURF?

LONSURF contains the active substances trifluridine and tipiracil.

- Trifluridine stops the growth of cancer cells.
- Tipiracil stops the trifluridine from being broken down by the body, helping trifluridine to work longer.

LONSURF is used to treat cancer by slowing down the growth and spread of cancer cells.

LONSURF is a type of cancer chemotherapy which belongs to a group of medicines called 'cytostatic antimetabolite medicines'.

LONSURF is used to treat adults with colon or rectal cancer - sometimes called 'colorectal' cancer. It is also used to treat gastric cancer - sometimes called 'stomach' cancer.

It is used when the cancer has spread to other parts of the body.

It is used when other treatments have not worked - or when other treatments are not suitable for you.

2. What should I know before I use LONSURF?

Warnings

Do not use LONSURF if:

- you are allergic to tipiracil and/or trifluridine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not take LONSURF after the expiry date printed on the pack.
- Do not take LONSURF if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have any other medical conditions especially the following:

- kidney problems
- LONSURF is not recommended in some patients with kidney problems. Before you start each treatment cycle of LONSURF, your doctor will perform blood tests to monitor your kidneys to see how they are working.
- liver problems.
- LONSURF is not recommended in some patients with liver problems. Before you start each treatment cycle of LONSURF, your doctor will perform blood tests to monitor your liver to see how your liver is working. Treatment with LONSURF may lead to a higher risk of liver problems.
- take any medicines for any other condition.
- LONSURF contains lactose.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

Pregnancy

Do not take this medicine if you are pregnant or think you might be pregnant.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most anti-cancer medicines, LONSURF is not recommended for use during pregnancy. However, if you need to take LONSURF during your pregnancy, your doctor will discuss with you the benefits and risks of taking it.

You must not become pregnant while taking LONSURF, as this medicine may harm your unborn baby.

Contraception

You and your partner should use effective methods of contraception while taking this medicine. You should also do this for 6 months after you stop taking the medicine. If you or your partner becomes pregnant during this time, you must talk to your doctor or pharmacist straight away.

Breastfeeding

Do not breast-feed while taking LONSURF.

Tell your doctor if you are breast-feeding or planning to breast-feed. This medicine may interfere with the growth and development of your baby.

Fertility

LONSURF may reduce fertility in both men and women. Your doctor will advise you of your options prior to starting treatment.

Children and adolescents

LONSURF is not recommended for use in children and adolescents. Safety and effectiveness have not been established in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

LONSURF and other medicines may interact. These include medicines used for treatment of HIV, such as zidovudine. Zidovudine may not work as well if you are taking LONSURF.

You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LONSURF.

4. How do I use LONSURF?

Always take LONSURF exactly as your doctor has told you to.

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

MyLonsurf Dosing Calendar

The MyLonsurf dosing calendar has been created to help you understand your dose and treatment cycle. The MyLonsurf dosing calendar also contains important information on how many tablets of each strength you need to take for your current four week cycle.

Ask your doctor if you have not received, or have misplaced, your MyLonsurf dosing calendar.

How much to take / use

- Your doctor or pharmacist will tell you how many tablets you will need to take each time. The dose depends on your weight and height and if you have kidney problems.
- LONSURF comes in two strengths. Your doctor may prescribe both strengths for your prescribed dose.
- You will take the dose two times a day - half the dose in the morning and half the dose at night.
- Swallow LONSURF tablets whole, with a glass of water.
- Wash your hands after handling LONSURF tablets.

When to take / use LONSURF

Your doctor will usually prescribe LONSURF for 10 days during the first two weeks and then stop for two weeks. This two week on, two weeks off treatment period is one 'cycle' of treatment.

The specific dosing schedule is as follows:

- Week 1 - take the dose two times a day for five days. Then have two days off - no medicine.
- Week 2 - take the dose two times a day for five days. Then have two days off - no medicine.
- Week 3 - no medicine.
- Week 4 - no medicine.

You will then begin another treatment cycle following the above pattern.

Take LONSURF immediately after your morning and evening meals, or within one hour after completion of your morning and evening meals.

How long to take it

Your doctor will continue to treat you with LONSURF as long as you are receiving benefit from therapy. Your doctor may need to reduce your dose or may decide to stop treatment if you experience serious side effects.

Do not stop taking it unless your doctor tells you to - even if you feel better.

If you do not understand the instructions provided, ask your doctor or pharmacist for help.

If you forget to use LONSURF

If you miss a dose, do not take the missed dose at a later date. Make a record of the dose you missed and tell your doctor and/or pharmacist immediately.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much LONSURF

If you think that you have used too much LONSURF, you may need urgent medical attention.

You should immediately do one of the following:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do one of the above even if there are no signs of discomfort or poisoning.

5. What should I know while using LONSURF?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking LONSURF.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking LONSURF.

Tell your doctor immediately if you become pregnant during treatment with LONSURF, or plan to become pregnant.

Tell your doctor if you are breast-feeding while being treated with LONSURF.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things you should not do

- Do not give LONSURF to anyone else, even if their symptoms seem similar or they have the same condition as you.
- Do not take LONSURF to treat any other complaints unless your doctor tells you to.
- Do not stop taking LONSURF, or lower the dosage, even if you are feeling better, without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LONSURF affects you.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Do not take LONSURF after the expiry date printed on the pack.

The expiry date is printed on the carton and bottle after "EXP" (e.g. 11 17 refers to November 2017). The expiry date refers to the last day of that month.

Do not take LONSURF if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. Sometimes they are serious, most of the time they are not. However, some side effects may need medical attention. You may need medical treatment if you get any of the side effects listed below, after taking LONSURF alone or in combination with another type of cancer chemotherapy, bevacizumab.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

| Serious side effects | What to do |
|--|--|
| <p>Skin</p> <ul style="list-style-type: none"> • sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body <p>Gastrointestinal</p> <ul style="list-style-type: none"> • vomiting and diarrhoea, which may lead to a dehydration if severe or persistent. • abdominal pain. The signs include intense stomach or abdominal pain that can be associated with vomiting, blocked or partly blocked bowel, fever or swelling of the abdomen. • severe gastrointestinal problems: ascites, colitis, acute pancreatitis, ileus and subileus. The signs include intense stomach or abdominal pain that can be associated with vomiting, blocked or partly blocked bowel, fever or swelling of the abdomen. <p>Respiratory and heart</p> <ul style="list-style-type: none"> • shortness of breath, wheezing or difficulty breathing • pulmonary embolism - blood clots in lungs. The signs include shortness of breath and pain in the chest or in the legs. <p>Blood and investigations</p> | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> neutropenia – a decreased number of white blood cells. The signs include chills, fever (febrile neutropenia), sweating or other sign of infection. anaemia - a condition in which there is a decreased number of red blood cells. The signs include feeling short of breath, tiredness or looking pale. thrombocytopenia - low blood platelet count. The signs include unusual bruising or bleeding. <p>Infections</p> <ul style="list-style-type: none"> septic shock. The signs include chills, fever, sweating or other sign of infection | |

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>Skin and hair</p> <ul style="list-style-type: none"> rash, itchy or flaky skin skin flushing dry skin raised itchy rash, hives, acne sweating more than normal and, nail problem raised red skin, blisters, skin sloughing off swelling of mucous membranes - this could be inside the nose, throat, eyes, vagina, lungs or gut sensitivity to light hair loss <p>Gastrointestinal</p> <ul style="list-style-type: none"> decreased appetite nausea - feeling sick constipation weight loss bloating, passing gas, indigestion inflammation in lower part of digestive tract swelling or bleeding in your bowel inflammation or increased acid in your stomach or gullet, reflux inflammation and infection in your gut inflammation in upper part of digestive tract pain in upper or lower part of digestive tract | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> inflammation or bleeding in your bowel increase in the diameter of the bile duct <p>Mouth and throat</p> <ul style="list-style-type: none"> changes in taste swelling of mucous membranes in mouth mouth pain or problems mouth ulcers painful tongue, retching bad breath, tooth decay, tooth problems, gum infections sore throat, hoarse voice, problems with your voice bad breath, gum problems, bleeding gums polyps inside your mouth <p>Kidney and liver related</p> <ul style="list-style-type: none"> increased bilirubin in your blood - can cause yellowing of skin or eyes increased liver enzymes protein in your urine liver disorder inflammation or infection of bile ducts. The signs may include pain on the right side of your stomach. kidney failure. The signs include little or no urine, drowsiness, nausea, vomiting, breathlessness blood in urine urine retention - problems passing water, incontinence - loss of bladder control inflammation in your bladder changes in urine test <p>Respiratory and heart</p> <ul style="list-style-type: none"> Interstitial lung disease has been reported in patients receiving the medicine in Japan. The signs include difficulty in breathing, shortness of breath, with cough or fever. cough, feeling short of breath, infection of the sinuses, throat, airway or lungs, chest infections more noticeable heart-beat, chest pain abnormal increase or decrease in heart rate accumulation of fluid in the lungs | |

| Less serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> ● changes in your heart trace (ECG - electrocardiogram) <p>Blood and investigations</p> <ul style="list-style-type: none"> ● reduced white blood cells called leucocytes - can increase your risk for infection ● low levels of albumin or total protein in the blood ● reduced number of white blood cells called lymphocytes - can increase your risk for infection ● blood test results indicating problems with clotting making you bleed more easily ● increased number of white blood cells called monocytes ● increased lactate dehydrogenase level in your blood ● low levels of phosphates, sodium, potassium or calcium in your blood ● reduced white blood cells called monocytes - can increase your risk for infection ● hyperglycaemia - high blood sugar, urea, creatinine and potassium in your blood ● blood test result indicating inflammation (C-Reactive Protein increased) ● reduced white blood cells called granulocytes - can increase your risk of infection ● increased salt in your blood ● blood clots, e.g. in the brain or legs ● low level of total protein in the blood <p>Infections</p> <ul style="list-style-type: none"> ● viral infection ● shingles - pain and vesicular rash on skin over nerve tracts affected by nerve inflammation from herpes zoster virus ● infections: bacterial or fungal ● infection in your bladder ● athlete's foot - fungal infection of feet, yeast infections <p>Musculoskeletal</p> <ul style="list-style-type: none"> ● swelling in your hands or legs or feet ● pain in your joints ● muscle pain | |

| Less serious side effects | What to do |
|--|------------|
| <ul style="list-style-type: none"> ● swelling or pain in your joints or big toes ● pain in your arms or legs ● pain, including pain from the cancer ● bone pain, muscle weakness or spasms, ● feeling of numbness or pins and needles in hands or feet ● redness, swelling, pain on the palms of your hands and soles of your feet (hand-foot syndrome) <p>Nervous system</p> <ul style="list-style-type: none"> ● feeling dizzy, headache ● low or high blood pressure ● vertigo - feeling of spinning ● anxiety ● problem with sleeping or falling asleep ● non-severe neurological troubles ● feeling lethargic or tired ● feeling dizzy, headache ● burning sensation, unpleasant, increased or loss of sense of touch ● fainting (syncope) <p>Eye, ear and nose</p> <ul style="list-style-type: none"> ● redness, itching of the eye, eye infections, watery eyes ● vision troubles as blurred vision, double vision, decreased vision, cataracts ● dry eyes ● ear pain ● runny or bloody nose, sinus problems <p>Reproductive system</p> <ul style="list-style-type: none"> ● changes in the menstrual cycle <p>General</p> <ul style="list-style-type: none"> ● dehydration ● fever ● fatigue - feeling very tired ● malaise - feeling generally out of sorts ● general feeling of discomfort ● feeling of being cold | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LONSURF contains

| | |
|---|---|
| Active ingredients (main ingredients) | Trifluridine Tipiracil (as hydrochloride) |
| Other ingredients (inactive ingredients) | Lactose monohydrate Pre-gelatinised starch Stearic acid Hypromellose Macrogol (8000) Titanium dioxide (E171) Magnesium stearate The printing ink contains: Shellac Iron oxide red (E172) Iron oxide yellow (E172), Titanium dioxide (E171) Indigo carmine aluminium lake (E132) Carnauba wax Talc |
| Potential allergens | Lactose |

Do not take this medicine if you are allergic to any of these ingredients.

What LONSURF looks like

LONSURF 15/ 6.14 is a white, biconvex, round, film-coated tablet, printed with "15" on one side and "102" and "15 mg" on the other side in grey ink.



(Tablet image not actual size)

LONSURF 20 /8.19 is a pale red, biconvex, round, film-coated tablet, printed with "20" on one side and "102" and "20 mg" on the other side in grey ink.



(Tablet image not actual size)

Each pack contains 20 film-coated tablets (2 blisters of 10 tablets each) or 60 film-coated tablets (6 blisters of 10 tablets each).

(AUST R 273239: LONSURF 15/6.14 tablets
AUST R 273238: LONSURF 20/8.19 tablets).

Who distributes LONSURF

Servier Laboratories (Aust.) Pty. Ltd.

www.servier.com.au

Level 4, Building 9

588A Swan Street

Burnley, 3121, Victoria

This leaflet was prepared in November 2024.