

LONSURF®

Trifluridine/Tipiracil Hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LONSURF. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking LONSURF against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine.

You may need to read it again.

What LONSURF is used for

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

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.

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

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.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is no evidence that LONSURF is addictive.

Before you take LONSURF

When you must not take it

Do not take LONSURF if you have an allergy to:

- **tipiracil and/or trifluridine (the active ingredients in LONSURF)**
- **any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to LONSURF may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives on the skin.

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

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

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.

If you are not sure whether you should start taking LONSURF, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

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.

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.

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

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.

Tell your doctor if you have or have had any 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking LONSURF.

Your doctor will carry out blood tests before each treatment cycle of LONSURF. They may also carry out other tests.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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.

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.

How to take 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

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.

How to take it

Swallow LONSURF tablets whole, with a glass of water.

Wash your hands after handling LONSURF tablets.

When to take it

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 take it

It is important that you take your prescribed dose as recommended by your doctor. If you have any questions or concerns about your medication, ask your doctor or pharmacist for help.

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 that you missed.

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

Tell your doctor or pharmacist about any missed dose.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too

much LONSURF. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much LONSURF it may make the side effects more severe, especially skin reactions (rash, blisters, redness, pain, swelling, itching or peeling of your skin).

While you are taking LONSURF

Things you must 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 must 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.

Things to be careful of

Do not drive or operate machinery until you know how LONSURF affects you. Speak with your doctor about when you can resume these activities.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LONSURF.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor immediately if you notice any of the following serious side effects (many of the side effects are usually only identified after blood tests - for example those affecting your blood cells). Your doctor will be looking out for these side effects in your test results:

Very common (may affect more than 1 in 10 people)

- neutropenia - lack of white blood cells. The signs include chills, fever, 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.
- vomiting and diarrhoea , which may lead to a dehydration if severe or persistent.
- thrombocytopenia - low blood platelet count. The signs include unusual bruising or bleeding.

Common (may affect up to 1 in 10 people)

- febrile neutropenia - a condition in which there is a decreased number of red blood cells and accompanied by fever. The signs include chills, fever, sweating or other sign of infection
- 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.

Uncommon (may affect up to 1 in 100 people)

- 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
- septic shock. The signs include chills, fever, sweating or other sign of infection
- pulmonary embolism - blood clots in lungs. The signs include shortness of breath and pain in the chest or in the legs.

Some of these serious side effects may lead to death.

Other side effects:

Many of the side effects are usually only identified after blood tests - for example those affecting your blood cells. Your doctor will be looking out for these side effects in your test results.

Very common (may affect more than 1 in 10 people)

- decreased appetite
- fatigue - feeling very tired
- nausea - feeling sick

- reduced white blood cells called leucocytes - can increase your risk for infection

Common (may affect up to 1 in 10 people)

- fever
- hair loss
- weight loss
- changes in taste
- constipation
- malaise - feeling generally out of sorts
- low levels of albumin or total protein in the blood
- increased bilirubin in your blood - can cause yellowing of skin or eyes
- reduced number of white blood cells called lymphocytes - can increase your risk for infection
- swelling in your hands or legs or feet
- hand-foot syndrome - redness, swelling, pain on the palms of your hands and soles of your feet
- feeling of numbness or pins and needles in hands or feet
- mouth pain or problems

- swelling of mucous membranes - this could be inside the nose, mouth, throat, eyes, vagina, lungs or gut
- increased liver enzymes
- protein in your urine
- rash, itchy or flaky skin
- cough, feeling short of breath, infection of the sinuses, throat, airway or lungs, chest infections

Uncommon (may affect up to 1 in 100 people)

- low or high blood pressure
- skin flushing
- blood clots, e.g. in the brain or legs
- blood test results indicating problems with clotting making you bleed more easily
- more noticeable heart-beat, chest pain
- abnormal increase or decrease in heart rate
- changes in your heart trace (ECG - electrocardiogram)
- 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 granulocytes or monocytes - can increase your risk for infection
- hyperglycaemia - high blood sugar, increased salt, urea, creatinine and potassium in your blood
- blood test result indicating inflammation (C-Reactive Protein increased)
- ear pain
- vertigo - feeling of spinning
- runny or bloody nose, sinus problems
- sore throat, hoarse voice, problems with your voice
- cough
- redness, itching of the eye, eye infections, watery eyes
- dry eyes
- vision troubles as blurred vision, double vision, decreased vision, cataracts
- dehydration
- bloating, passing gas, indigestion
- pain or inflammation in upper or lower part of digestive tract
- inflammation, swelling or bleeding in your bowel

- inflammation and infection in your gut
- inflammation or increased acid in your stomach or gullet, reflux
- painful tongue, polyps inside your mouth, mouth ulcers, retching
- bad breath, tooth decay, tooth or gum problems, bleeding gums, gum infections
- dry skin
- general feeling of discomfort
- swelling or pain in your joints or big toes
- pain in your arms or legs
- pain, including pain from the cancer
- bone pain, muscle pain, muscle weakness or spasms, pain in tendons, nerves or ligaments
- feeling of being cold
- shingles - pain and vesicular rash on skin over nerve tracts affected by nerve inflammation from herpes zoster virus
- liver disorder
- inflammation or infection of bile ducts, increase in the diameter of the bile duct. 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
- infections: bacterial, viral or fungal
- inflammation or infection in your bladder
- changes in urine test, blood in urine
- urine retention - problems passing water, incontinence - loss of bladder control
- athlete's foot - fungal infection of feet, yeast infections
- pulmonary oedema - accumulation of fluid in the lungs. The signs include breathlessness, which may be very severe and usually worsens on lying down
- changes in the menstrual cycle
- anxiety
- problem with sleeping or falling asleep.
- syncope - passing out
- burning sensation, unpleasant, increased or loss of sense of touch and other non-severe neurological troubles
- feeling lethargic or tired
- feeling dizzy, headache
- raised itchy rash, red skin, blisters, skin sloughing off, hives, acne

- sweating more than normal, sensitivity to light, nail problems.

If any of the following happen, do not take your next dose of LONSURF before telling your doctor or going to Accident and Emergency at your nearest hospital:

- sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

- 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using LONSURF

Storage

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it

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

Disposal

If your doctor tells you to stop taking LONSURF or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it 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.

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.

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

Ingredients

Active ingredients:

- Trifluridine
- Tipiracil (as hydrochloride)

Other ingredients:

LONSURF 15 /6.14 and LONSURF 20 /8.19 film-coated tablets contain:

Lactose monohydrate, pre-gelatinised starch, stearic acid, hypromellose, macrogol (8000), titanium dioxide (E171) and 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 and talc.

LONSURF 20 /8.19 film-coated tablets also contain iron oxide red (E172).

LONSURF contains lactose.

Sponsor

LONSURF is supplied in Australia by:

Servier Laboratories (Aust.) Pty. Ltd.

Level 4, Building 9,

588A Swan Street

Burnley 3121 Victoria

Telephone: 1800 153 590

Internet: www.servier.com.au

Australian Registration Number

AUST R 273239: LONSURF 15/6.14 tablets

AUST R 273238: LONSURF 20/8.19 tablets

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See your doctor, pharmacist or the TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.