#### **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 <u>1. Why am I using LONSURF?</u> 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 CML

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 <u>4. How do I</u> use LONSURF? in the full CMI.

# 5. What should I know while using LONSURF?

## Things you should do

- 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

- 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> <li>Do not drive or operate machinery until you know how LONSURF affects you. Speak with your doctor about when you can resume these activities.</li> </ul>
Looking after your medicine	<ul> <li>Store in a cool dry place away from moisture, heat and sunlight. Keep out of reach of children.</li> <li>Keep your tablets in the pack until it is time to take them.</li> </ul>

For more information, see Section <u>5. What should I know while using LONSURF?</u> 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 <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

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 <u>6</u>. 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	
• sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body	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.	
Gastrointestinal		
<ul> <li>vomiting and diarrhoea, which may lead to a dehydration if severe or persistent.</li> </ul>		
<ul> <li>abdominal pain.         The signs include intense stomach or abdominal pain that can be associated with vomiting, blocked or partly blocked bowel,     </li> </ul>		

Serious side effects	What to do
fever or swelling of the abdomen.	
<ul> <li>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.</li> </ul>	
Respiratory and heart	
<ul> <li>shortness of breath, wheezing or difficulty breathing</li> </ul>	
<ul> <li>pulmonary embolism - blood clots in lungs. The signs include shortness of breath and pain in the chest or in the legs.</li> </ul>	
Blood and investigations	
<ul> <li>neutropenia – a decreased number of white blood cells. The signs include</li> </ul>	

Serious side effects	What to do
chills, fever (febrile neutropenia), sweating or other sign of infection.	
<ul> <li>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.</li> <li>thrombocytopenia - low blood platelet count. The</li> </ul>	
signs include unusual bruising or bleeding.	
Infections	
<ul> <li>septic shock. The signs include chills, fever, sweating or other sign of infection</li> </ul>	

## Less serious side effects

Less seriou side effects	
Skin and hair	Speak to your
<ul> <li>rash itchy or flaky skin</li> <li>skin flush</li> <li>dry skin</li> <li>raise itchy rash hive</li> </ul>	doctor if you have any of these less serious

·	1		1
L	ess	What	
S	eriou	so do	
S	ide		
e	ffects	8	
	nail		
	prok		
•	raise		
	red		
	skin		
	blist		
	skin		
	slou		
	off		
•	swe		
	of		
	muc		
	men		9
	-		
	this		
	coul		
	be .		
	insid		
	the		
	nose		
	eyes		
	lung		
	or		
	gut		

si si	ess eriou ide ifects	What so do	
•	sens to light hair loss		
G •	deci appo naus - feeli		na
•	sick cons weig loss bloa		n
•	pass gas, indig inflatin lower part		on

SS	What	
riou	so do	
de		
fects	5	
diae		
tract		
swe		
or		
blee		
in		
youi		
bow		
infla		on
or		
incr		
acid		
in		
youi		
ston		
or		
infla		bn
_		
		pn
upp		
	dige dige dige dige dige dige dige dige	riou sto do de fects dige tracts we or blee in your bow infla or increacid in your stor or gulle refluinfla and inferingul gut infla in

	1	
L	ess	What
		so do
	ide	
	ffects	<b>S</b>
	part	
	of	
	dige	
	trac	
•	Pani	
	in	
	upp	
	or	
	lowe	
	part	
	of	
	dige	
	tract	
•	infla	
	or	
	blee	
	in	
	you	
	bow	
•	incr	
	in	
	the	
	dian	
	of	
	the	
	bile	
	duct	
	uuci	

			1
L	ess	What	
S	eriou	so do	
S	ide		
e	ffects	5	
			ĺ
	louth		
	nd		
tr	roat		
•	chai		
	in		
	tast		
•	swe		
	of		
	muc		
	men		S
	in		
	mou		
•	mou		
	pain		
	or		
	prok		
•	mou		
	ulce		
•	pain		
	tong		
	retc		
•	bad		
	brea		
	toot		
	deca		
	toot		
l		l	ĺ

•	
Less	What
seriou	so do
side	
effects	5
nrok	
prok	
gum infe	
sore	
thro	
hoai	
voic	
prok	
with	
you	
voic	
• bad	
brea	
gum	
prob	
blee	
gum	
• poly	
insi	
you	
mou	
Kidne	
and	
liver	
related	

			l
S	ess eriou ide	What so do	
e	ffects	5	
•	incre bilir		
	in you		
	bloc		
	can		
	yello		
	of		
	skin		
	or		
	eyes		
•	incr		
	liver		
•	enzy		
	prot in		
	you		
	urin		
•	liver		
	diso		
•	infla		bn
	or infe		
	of		
	bile		

		1
Less	What	
seriou	<b>s</b> o do	
side		
effects	5	
duct		
The		
sign		
may		
incl		
pain		
on		
the		
righ		
side		
of		
you		
ston		
• kidn		
failu		
The		
sign		
incl		
little		
or		
no		
urin		
drov		۶,
naus		
vom		
brea		ness
ı	ı	•

		_	
L	ess	What	
S	eriou	so do	
S	ide		
e	ffects	5	
	bloc		
	in		
	urin		
	urin		
	rete		
	prok		
	pass		
	wate		
	inco		ce
	-		
	loss		
	of		
	blad		
	cont		
•	infla		on
	in		
	you		
	blad		
•	chai		
	in		
	urin		
	test		
R	espi		
a	nd		
h	eart		

## What Less seriouso do side effects Inter lung dise has beei repo in patie rece the med in Japa The sign incl diffi in brea sho of brea with cou or feve cou feeli

## What Less seriouso do side effects sho of brea infe of the sinu thro airw or lung ches infe • mor noti hear beat ches pain • abn incr or deci in hear rate

Less What	
seriouso do	
side	
effects	
enecis	
• accı	on
of	
fluid	
in	
the	
lung	
• chai	
in	
you	
hear	
trac	
(EC	
-	
elec	liogram)
Blood	
and	
invest	S
• redu	
whit	
bloc	
cells	
calle	
leuc	
-	
can	
incr	
you	

Less	What	
seriou	so do	
side		
effects	<b>5</b>	
risk		
for		
infe		
• low		
leve		
of		
albu		
or tota		
prot   in	•	
the		
bloc		
• redu		
num		
of		
whit		
bloc		
cells		
calle		
lym		es
_		
can		
incr		
you		
risk		
·	•	•

			1
L	ess	What	
S	eriou	so do	
S	ide		
ef	ffects	5	
	for		
	infe		
•	bloc		
	test		
	resu		
	indi		
	prob		
	with		
	clot		
	mak		
	you		
	blee		
	mor		
	easi		
•	incr		
	num		
	of		
	whit		
	bloc		
	cells		
	calle		
	mor		•
•	incr		
	lacta		
	deh		nase
	leve		
	in		
•		•	•

What Less seriouso do side effects you bloc • low leve of pho s, sodi pota or calc in you bloc • redu whit bloc cells calle mon can incr you risk for infe

			1
L	ess	What	
S	eriou	so do	
S	ide		
e	ffects	8	
•	hyp		emia
	-		
	high		
	bloc		
	suga		
	urea		
	crea		
	and		
	pota		
	in		
	you		
	bloc		
•	bloc		
	test		
	resu		
	indi		
	infla		on
	(C-		
	Rea		
	Prot		
	incr		
•	redu		
	whit		
	bloc		
	cells		
	calle		
	gran		es

Less	What
seriou	so do
side	
effect	\$
_	
can	
incr	
you	
risk	
of	
infe	
• incr	
salt	
in	
you	1
bloc	
• bloc	
clot	
e.g.	
in	
the	
brai	
or	
legs	
• low	
leve	
of	
tota	
prot	
in	
•	1

	1	1
Less seriou	What so do	
side		
effect	\$	
the		
bloc		
	1	
Infect		
• vira	ļ	
infe		
• shir	1	
-		
pair	1	
and		
vesi		
rasł	1	
on		
skin		
ove	İ	
nerv		
trac		
affe		
by		
ner	1	
infla		pr
fron		
herp		
ZOSI		
viru		
• infe		
bact	9	

			Ī
L	ess	What	
S	eriou	so do	
s	ide		
e	ffects	5	
	or		
	fung		
•	infe		
	in		
	you		
•	athle		
	foot		
	-		
	fung		
	infe		
	of		
	feet.		
	yeas		
	infe		
			-4-1
	luscı		etal
•	swe		
	in		
	you		
	hand		
	or		
	legs		
	or		
	feet		
•	pain		
	in		

### What Less seriouso do side effects you joint • mus pain • swe or pain in you joint or big toes pain in you arm or legs pain inclu pain fron the can • bon pain

L	ess	What
S	eriou	so do
S	ide	
e	ffects	\$
	mus	
	wea	
	or	
	spas	
•	feeli	
	of	
	num	
	or	
	pins	
	and	
	need	
	in	
	hane	
	or	
	feet	
•	redr	
	swe	
	pain	
	on	
	the	
	paln	
	of	
	you	
	hand	
	and	
	sole	
	of	
	you	

Less seriou side effects	
feet (han foot	
Nervo syster	
• feeli dizz head	
• low or high	
pres • verti	
feeli of spin	
• anxi	
<ul><li>prok</li><li>with</li><li>slee</li><li>or</li><li>fallii</li></ul>	
asle	

### What Less seriouso do side effects • nonseve al neui trou • feeli letha or tired • feeli dizz head burr sens unp incr or loss of sens of touc faint (syn

Less	What
seriou	so do
side	
effects	\$
Eye,	
ear	
and	
nose	
• redr	
itchi	
of the	
the	
eye,	
eye infe	
wate	
eyes	
• visio	
trou	
as	
as blur	
visio	
dou	
visio	
deci	
visio	
cata	
• dry	
eyes	
• ear	
pain	
Paili	

# What Less seriouso do side effects • runr or blod nos sinu prot Repro syster • char in the men cycl Gener dehy feve fatig feeli very tirec mala feeli gen

Less seriou side effects	
out of sort	
<ul><li>general general genera</li></ul>	
• feeli of bein 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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	Lactose monohydrate
(inactive ingredients)	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
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.