

Package leaflet: Information for the patient

Trifluridine/Tipiracil Servier 15 mg/6.14 mg film-coated tablets

Trifluridine/Tipiracil Servier 20 mg/8.19 mg film-coated tablets

trifluridine/tipiracil

Read all of this leaflet carefully before you start taking this medicine - because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What trifluridine/tipiracil is and what it is used for
2. What you need to know before you take trifluridine/tipiracil
3. How to take trifluridine/tipiracil
4. Possible side effects
5. How to store trifluridine/tipiracil
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1. What trifluridine/tipiracil is and what it is used for

Trifluridine/Tipiracil is a type of cancer chemotherapy which belongs to the group of medicines called "cytostatic antimetabolite medicines".

Trifluridine/Tipiracil 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.

Trifluridine/Tipiracil is used to treat adults with colon or rectal cancer - sometimes called 'colorectal' cancer and stomach cancer (including cancer of the junction between the oesophagus and the stomach).

- It is used when the cancer has spread to other parts of the body (metastases).
- It is used when other treatments have not worked - or when other treatments are not suitable for you.

Trifluridine/Tipiracil may be given in combination with bevacizumab. It is important that you also read the package leaflet of bevacizumab. If you have any questions about this medicine, ask your doctor.

2. What you need to know before you take trifluridine/tipiracil

Do not take trifluridine/tipiracil

- if you are allergic to trifluridine or tipiracil or any of the other ingredients of this medicine (listed in section 6).

Do not take trifluridine/tipiracil if the above applies to you. If you are not sure, talk to your doctor before taking trifluridine/tipiracil.

Warnings and precautions

Talk to your doctor or pharmacist before taking trifluridine/tipiracil if:

- you have kidney problems
- you have liver problems

If you are not sure, talk to your doctor or pharmacist before taking Trifluridine/Tipiracil.

Treatment may lead to the following side effects (see section 4):

- a reduced number of certain types of white blood cells (neutropenia) which are important for protecting the body against bacterial or fungal infections. As a consequence of neutropenia, fever (febrile neutropenia) and blood infection (septic shock) may occur
- a reduced number of red blood cells (anaemia)
- a reduced number of platelets in the blood (thrombocytopenia) which are important to stop bleeding and work by clumping and clotting blood vessel injuries
- gastrointestinal problems.

Tests and checks

Your doctor will do blood tests before each cycle of trifluridine/tipiracil. You start a new cycle every 4 weeks. The tests are needed because trifluridine/tipiracil can sometimes affect your blood cells.

Children and adolescents

This medicine is not indicated for use in children and adolescents below the age of 18 years. This is because it may not work or be safe.

Other medicines and trifluridine/tipiracil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription and herbal medicines. This is because trifluridine/tipiracil can affect the way some other medicines work. Also some other medicines can affect the way trifluridine/tipiracil works.

In particular tell your doctor or pharmacist if you are taking medicines used for treatment of HIV, such as zidovudine. This is because zidovudine may not work as well if you are taking trifluridine/tipiracil. Talk to your doctor about whether to switch to a different HIV medicine.

If the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking trifluridine/tipiracil.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, or if you think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Trifluridine/Tipiracil may harm your unborn baby.

If you become pregnant, you and your doctor will have to decide if the benefits of trifluridine/tipiracil are greater than the risk of harm to the baby.

Do not breast-feed if you are taking trifluridine/tipiracil as it is not known whether trifluridine/tipiracil passes into the mother's milk.

Contraception

You must not become pregnant while taking this medicine. This is because it 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 become pregnant during this time, you must talk to your doctor or pharmacist straight away.

Fertility

Trifluridine/Tipiracil may affect your ability to have a baby. Talk to your doctor for advice before using it.

Driving and using machines

It is not known whether trifluridine/tipiracil changes your ability to drive or use machines. Do not drive or use any tools or machines if you experience symptoms that affect your ability to concentrate and react.

Trifluridine/Tipiracil 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.

3. How to take trifluridine/tipiracil

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

- Your doctor will decide the right dose for you - the dose depends on your weight and height and if you have kidney problems.
- Trifluridine/Tipiracil comes in two strengths. Your doctor may prescribe both strengths for your prescribed dose.
- Your doctor will tell you how many tablets to take each time.
- You will take a dose 2 times a day.

When to take trifluridine/tipiracil

You will take trifluridine/tipiracil for 10 days during the first 2 weeks, and then have 2 weeks off. This 4-week period is called a 'cycle.' The specific dosing schedule is as follows:

- **Week 1**
 - take the dose 2 times a day for 5 days
 - then have 2 days off - no medicine
- **Week 2**
 - take the dose 2 times a day for 5 days
 - then have 2 days off - no medicine
- **Week 3**
 - No medicine
- **Week 4**
 - No medicine

You will then start again with another cycle of 4 weeks following the above pattern.

How to take

- Take this medicine by mouth.
- Swallow the tablets whole with a glass of water.
- Take within 1 hour after your morning and evening meals.
- Wash your hands after handling this medicine.

If you take more trifluridine/tipiracil than you should

If you take more trifluridine/tipiracil than you should, talk to a doctor or go to a hospital straight away. Take your pack(s) of medicine with you.

If you forget to take trifluridine/tipiracil

- If you forget a dose, talk to your doctor or pharmacist.
- Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine when it is taken alone or in combination with bevacizumab:

Serious side effects

Tell your doctor immediately if you notice any of the following serious side effects (many of the side effects are shown in laboratory tests - for example those affecting your blood cells):

- Neutropenia (*very common*), febrile neutropenia (*common*) and septic shock (*rare*). The signs include chills, fever, sweating or other signs of bacterial or fungal infection (see section 2).
- Anaemia (*very common*). The signs include feeling short of breath, tiredness or looking pale (see section 2).
- Vomiting (*very common*) and diarrhoea (*very common*), which may lead to a dehydration if severe or persistent.

- Severe gastrointestinal problems: abdominal pain (*common*), ascites (*rare*), colitis (*uncommon*), acute pancreatitis (*rare*), ileus (*uncommon*) and subileus (*rare*). 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.
 - Thrombocytopenia (*very common*). The signs include unusual bruising or bleeding (see section 2).
 - Pulmonary embolism (*uncommon*): blood clots in lungs. The signs include shortness of breath and pain in the chest or in the legs.
 - 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.
- Some of these serious side effects may lead to death.

Other side effects

Tell your doctor if you notice any of the following side effects. Many of the side effects are shown in laboratory 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
- feeling very tired (fatigue)
- feeling sick (nausea)
- reduced white blood cells called leucocytes - can increase your risk for infection
- swelling of mucous membranes in mouth

Common: may affect up to 1 in 10 people:

- fever
- hair loss
- weight loss
- changes in taste
- constipation
- feeling generally out of sorts (malaise)
- low level of albumin 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
- mouth pain or problems
- swelling of mucous membranes - this could be inside the nose, throat, eyes, vagina, lungs or gut
- increased liver enzymes
- protein in your urine
- rash, itchy or dry skin
- feeling short of breath, airway or lungs, chest infections
 - viral infection
 - pain in your joints
 - feeling dizzy, headache
 - high blood pressure
 - mouth ulcers
 - muscle pain

Uncommon: may affect up to 1 in 100 people

- low blood pressure
- 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
- increased white blood cells
- 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
- high blood sugar (hyperglycaemia), increased urea, creatinine and potassium in your blood
- blood test result indicating inflammation (C-Reactive Protein increased)
- feeling of spinning (vertigo)
- runny or bloody nose, sinus problems
- sore throat, hoarse voice, problems with your voice
- redness, itching of the eye, eye infections, watery eyes
- dehydration
- 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
- painful tongue, retching
- tooth decay, tooth problems, gum infections
- skin flushing
- pain or discomfort in your arms or legs
- pain, including pain from the cancer
- bone pain, muscle pain, muscle weakness or spasms
- 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
- kidney failure
- cough, infection of the sinuses, throat infections
- infection in your bladder
- blood in urine
- problems passing water (urine retention), loss of bladder control (incontinence)
- changes in the menstrual cycle
- anxiety
- non-severe neurological troubles
- raised itchy rash, hives, acne
- sweating more than normal, nail problems
- problem with sleeping or falling asleep
 - 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)

Rare: may affect up to 1 in 1 000 people

- inflammation and infection in your gut
- athlete's foot - fungal infection of feet, yeast infections
- reduced white blood cells called granulocytes - can increase your risk for infection
- swelling or pain in your big toes
- swelling in your joints
- increased salt in your blood
- burning sensation, unpleasant, increased or loss of sense of touch
- fainting (syncope)
- vision troubles as blurred vision, double vision, decreased vision, cataracts
- dry eyes
- ear pain
- inflammation in upper part of digestive tract
- pain in upper or lower part of digestive tract
- accumulation of fluid in the lungs
- bad breath, gum problems, bleeding gums
- polyps inside your mouth

- inflammation or bleeding in your bowel
- increase in the diameter of the bile duct
- raised red skin, blisters, skin sloughing off
- sensitivity to light
- inflammation in your bladder
- changes in urine test
- blood clots, e.g. in the brain or legs
- changes in your heart trace (ECG - electrocardiogram)
- low level of total protein in the blood

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store trifluridine/tipiracil

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton or blister after “EXP.” The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What trifluridine/tipiracil contains

Trifluridine/Tipiracil 15 mg/6.14 mg film-coated tablet

- The active substances are trifluridine and tipiracil. Each film-coated tablet contains 15 mg trifluridine and 6.14 mg tipiracil.
- The other ingredients are:
 - Tablet core: lactose monohydrate, starch pregelatinised (maize) and stearic acid (see section 2 “Lonsurf contains lactose”).
 - Film coat: hypromellose, macrogol (8000), titanium dioxide (E171), and magnesium stearate.
 - Printing ink: shellac, iron oxide red (E172), iron oxide yellow (E172), titanium dioxide (E171), indigo carmine aluminium lake (E132), carnauba wax and talc.

Trifluridine/Tipiracil 20 mg/8.19 mg film-coated tablet

- The active substances are trifluridine and tipiracil. Each film-coated tablet contains 20 mg trifluridine and 8.19 mg tipiracil.
- The other ingredients are:
 - Tablet core: lactose monohydrate, starch pregelatinised (maize) and stearic acid (see section 2 “Lonsurf contains lactose”).
 - Film coating: hypromellose, macrogol (8000), titanium dioxide (E171), iron oxide red (E172) and magnesium stearate.
 - Printing ink: shellac, iron oxide red (E172), iron oxide yellow (E172), titanium dioxide (E171), indigo carmine aluminium lake (E132), carnauba wax and talc.

What Trifluridine/Tipiracil looks like and contents of the pack

- Trifluridine/Tipiracil 15 mg/6.14 mg 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.

- Trifluridine/Tipiracil 20 mg/8.19 mg 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 40 film-coated tablets (4 blisters of 10 tablets each), or 60 film-coated tablets (6 blisters of 10 tablets each). A desiccant is incorporated into each blister foil.

Not all pack sizes may be marketed.

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