

TS-ONE[®] OD Tablet

Tegafur/Gimeracil/Oteracil Potassium (20mg/5.8mg/19.6mg, 25mg/7.25mg/24.5mg)

What is in this leaflet

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

Keep this Leaflet. You may need to read it again.

What TS-ONE[®] OD Tablet is used for

This medicine is used to treat adults with:

- Advanced gastric (stomach) cancer when given in combination with cisplatin (another anticancer medicine).
- Locally advanced (stage II (excluding T1), IIIA or IIIB) gastric (stomach) cancer as postoperative adjuvant chemotherapy.
- Locally advanced or metastatic pancreatic cancer when given as monotherapy.
- Locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin (another anticancer medicine).
- Metastatic colorectal cancer when given in combination with oxaliplatin (another anticancer medicine) as first-line treatment or in combination with irinotecan (another anticancer medicine) as second-line treatment.
- For the treatment of HER2-negative metastatic breast cancer when given as monotherapy.

- Hormone receptor (HR)-positive and human epidermal growth factor 2 (HER2)-negative breast cancer at high risk of recurrence as postoperative chemotherapy.

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.

How TS-ONE[®] OD Tablet works

TS-ONE[®] OD Tablet belongs to the fluoropyrimidine class of medicine known as “antineoplastic agents” which stop the growth of cancer cells.

Before you use TS-ONE[®] OD Tablet

- When you must not use it

Do not take TS-ONE[®] OD Tablet if you:

- are allergic (hypersensitive) to tegafur, gimeracil, oteracil or any of the other ingredients of TS-ONE[®] OD Tablet
- are taking other fluoropyrimidine anti-cancer medicine such as fluorouracil and capecitabine, or have had severe and unexpected reactions to fluoropyrimidines
- have known genetic deficiency of the enzyme dihydropyrimidine dehydrogenase (DPD)
- are pregnant or breastfeeding
- have severe blood disorders
- have kidney disease requiring dialysis
- have severe liver disorder
- are currently being treated or have been treated in the last 4 weeks with brivudine or a similar class of anti-viral medicines
- are taking flucytosine

- Before you start to use it

Before treatment with TS-ONE[®] OD Tablet, tell your doctor if you have any of the following:

- blood disorders
- kidney disease
- liver disease

- current or past history of hepatitis B virus infection
- infectious disease
- current or past history of interstitial pneumonia
- heart disease or history of heart disease
- gastrointestinal ulcers or bleeding
- stomach and/or bowel problems such as pain, diarrhoea, vomiting and dehydration
- eye disorders, such as “dry eye” or increased tearing
- TS-ONE[®] OD Tablet is not recommended for children under 18 years of age.
- TS-ONE[®] OD Tablet cannot be substituted for other oral fluoropyrimidine medicine.

- Taking other medicines

Before starting treatment, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is extremely important, as taking more than one medicine at the same time can strengthen or weaken the effect of the medicines. You need to be particularly careful if you are taking any of the following:

- other fluoropyrimidine-based medicines such as the anti-fungal flucytosine
- anti-virals such as brivudine
- inhibitors of the enzyme CYP2A6 which activates TS-ONE[®] OD Tablet such as tranlycypromine and methoxsalen
- folic acid (often used in chemotherapy with methotrexate)
- blood-thinning medicines: coumarin- derivative anticoagulants such as warfarin
- medicines for the treatment of seizures or tremors such as phenytoin
- medicines that treat gout such as allopurinol.

How to use TS-ONE[®] OD Tablet

- How much to use

Always take TS-ONE[®] OD Tablet exactly as your doctor has told you. You should check with your doctor if you are not sure.

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Your doctor will tell you what dose you need to take, when to take it and for how long you need to take it. Your dose of TS-ONE[®] OD Tablet will be determined by your doctor based on your height and weight. Your doctor may reduce the dose if you have side effects that are too severe.

- When to use it

TS-ONE[®] OD Tablet can be taken with or without water after a meal. When the drug is placed on the tongue, saliva can infiltrate into the drug to disintegrate it, therefore the drug can be taken without water.

Otherwise, the drug can also be taken with water. TS- ONE[®] OD Tablet must be taken twice daily (morning and evening).

Do not take the medicine without water while in lying position.

- How long to use it

1. For the treatment of advanced gastric (stomach) cancer when given in combination with cisplatin:

Take TS-ONE[®] OD Tablet for 21 consecutive days, combined with cisplatin on Day 8, followed by a 14-day rest period (1 treatment cycle). This treatment is repeated every 5 weeks.

2. As monotherapy for the treatment of locally advanced or metastatic pancreatic cancer, for post-operative adjuvant chemotherapy for locally advanced gastric (stomach) cancer or for the treatment of HER2-negative metastatic breast cancer:

Take TS-ONE[®] OD Tablet for 28 consecutive days, followed by a 14-day rest period (1 treatment cycle). This treatment is repeated every 6 weeks.

3. For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin:

Take TS-ONE[®] OD Tablet for 14 consecutive days, combined with carboplatin on Day 1, followed by a 7-day rest period (1 treatment cycle). This treatment is repeated every 3 weeks.

4. For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment:

- (i) Take TS-ONE[®] OD Tablet for 14 consecutive days, combined with oxaliplatin on Day 1, followed by a 7-day rest period (1 treatment cycle). This treatment is repeated every 3 weeks.

- (ii) Take TS-ONE[®] OD Tablet for 14 consecutive days, combined with irinotecan on Day 1 and 15, followed by a 14-day rest period (1 treatment cycle). This treatment is repeated every 4 weeks.

5. For postoperative adjuvant chemotherapy for HR-positive and HER2-negative breast cancer at high risk of recurrence

Take TS-ONE[®] OD Tablet for 14 consecutive days followed by a 7-day rest, in combination with endocrine therapy. This treatment cycle is repeated every 3 weeks. This is regarded as one course of the regimen and is continued for up to 1 year.

- If you forget to use it

Do not take the missed dose at all and do not double the next one. Instead, continue your regular dosing schedule and check with your doctor.

- If you use too much (overdose)

If you take more tablets than you should, contact your doctor immediately.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving TS-ONE[®] OD Tablet.

During the treatment, laboratory tests (blood tests, liver and renal function tests) are performed regularly at least once every 2 weeks to detect asymptomatic side effects as early as possible. Be sure to consult your doctor.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are receiving TS-ONE[®] OD Tablet.

Tell all the doctors, dentists and pharmacists treating you that you are taking TS-ONE[®] OD Tablet.

If you are going to have surgery, tell the surgeon or anaesthetist that you are having this medicine. It may affect other medicines used during surgery.

During and up to 6 months after treatment with TS-ONE[®] OD Tablet, you must use contraceptive measures. If you become pregnant during this time, you must tell your doctor.

You must not breastfeed if you are taking TS-ONE[®] OD Tablet.

Ask your doctor or pharmacist for advice before taking any medicine.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give TS-ONE[®] OD Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

Use caution when driving or operating a machine, as TS-ONE[®] OD Tablet may make you tired, nauseous or have

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blurred vision. If you have any doubts, talk to your doctor.

Important information about some of the ingredients of TS-ONE[®] OD Tablet

This medicine contains lactose (one type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Side effects

Like all medicines, TS-ONE[®] OD Tablet can cause side effects, although not everybody gets them.

While some symptoms are easily identified as side effects by the patients themselves, a blood test is required to identify some other symptoms. Your doctor will discuss this with you and will explain the possible risks and benefits of the treatment.

If you are concerned about the side effects below, talk to your doctor.

Very common side effects (affect more than 1 user in 10) include:

- Diarrhoea, nausea, vomiting, constipation
- If you experience diarrhoea more than 4 times a day or in the middle of the night, or if you experience mouth sores accompanied by diarrhoea, stop taking TS-ONE[®] OD Tablet and contact your doctor immediately.
- If you experience diarrhoea, avoid high-fibre, fatty and spicy foods.
- Take plenty of liquids between meals to replace lost fluids and prevent dehydration, low blood volume, and imbalance of salts or chemicals in the blood.
- If you experience nausea and vomiting after a dose of medication, make sure you tell your doctor. Do not replace the dose.
- If you vomit more than two times in 24 hours, stop taking TS-ONE[®] OD Tablet and contact your doctor immediately.
- To help manage nausea and vomiting:

- Lie down or take deep breaths when feeling nauseous
- Avoid tight clothing

- Low red blood cell count leading to anaemia
 - You may have symptoms such as cold hands and feet, looking pale, light-headedness, fatigue, breathlessness.
 - If you experience any of the above-mentioned symptoms, try not to work too hard and get ample sleep and rest.

- Low white blood cell count leading to increased risk of severe local (e.g. oral, lung, urine) or blood infections
 - You may have symptoms such as fever, chills, coughing, sore throat.
 - If you have fever of 38.5°C or higher, stop taking TS-ONE[®] OD Tablet and contact your doctor immediately.
 - To prevent infection, keep away from crowded places, gargle upon returning home, and wash your hands before meals and before and after using the bathroom.

- Low platelet count leading to an increased chance of bleeding
 - If you have bleeding of the skin, mouth (caused by brushing teeth), nose, respiratory tract, stomach, and gut, stop taking TS-ONE[®] OD Tablet and contact your doctor immediately.
 - To prevent bleeding, avoid hard work or strenuous sports so as to prevent injuries and bruises. Wear loose clothing to protect the skin. Brush your teeth and blow your nose gently.

- Loss of appetite (anorexia) can lead to weight loss and dehydration
 - You may become dehydrated if you do not eat and/or drink enough water.
 - If you become dehydrated, you may have symptoms such as dry mouth, weakness, dry skin, dizziness, cramping.
 - Try to eat frequent small meals. Avoid fatty and strong-smelling food as this may trigger nausea and worsen your appetite. Warm foods tend to have stronger odor. If the smell of the food bothers you, opt for cold or room-temperature food. Even if you do not feel hungry, continue to eat as much as you can to maintain good nutrition.

- If you feel tired and have fever together with loss of appetite, contact your doctor immediately.
- Nerve disorder: you may feel numbness, tingling, pain, abnormal sensation, weak muscle, shaking, or movement difficulties.
- Weakness and fatigue, which could be side effects caused by other medicines.

Common side effects (affect 1 to 10 users in 100) include:

- Nerve: headache, dizziness, sleeplessness, changes in taste
- Eye: eye problems, increased or decreased tearing discomfort, vision problems, mild to severe pain of the eye due to corneal erosion.
- Ear: hearing problems
- Blood vessels: high or low blood pressure, blood clots in the leg and lung
- Lung and nasal passages: shortness of breath, cough
- Gut and mouth: dry mouth, sores in mouth, throat, and oesophagus, hiccups, abdominal pain, indigestion, stomach or bowel inflammation, perforation of the stomach, small intestine, and large bowel
- Liver: yellow eyes and skin, changes in liver enzymes.
- Skin: hair loss, itchiness, rash or dermatitis, skin reaction, dry skin, hand-and-foot reaction (pain, swelling and redness of hands and/or feet), pigmented skin patches
- Kidney: decreased urine volume, kidney impairment and failure
- Other: chills, weight decrease, swelling in specific areas and muscle bone pain

Uncommon side effects (affect 1 to 10 users in 1,000) include:

- Mental: seeing and hearing some things that are not there, personality change, unable to sit still, confusion, feeling of nervousness, depression, sexual dysfunction
- Nerve: voice disorder, inability to speak and understand words, memory problem, unsteady gait, balance problems, one sided body weakness, sleepiness, nerve inflammation, distorted sense of smell, brain dysfunction, fainting,

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- loss of consciousness, stroke, seizures
- Eye: itchy and red eyes, allergic reactions in eyes, drooping upper eyelid
- Ear: vertigo, ear clogging, ear discomfort
- Heart: irregular or fast heartbeat, chest pain, accumulation of excess fluid around the heart, heart attack, heart failure
- Blood vessels: inflammation of a vein, hot flush
- Lung and nasal passages: runny nose, voice disorder, nasal clogging, pharyngeal erythema, hay fever
- Gut and mouth: fluid in the abdomen, gastroesophageal reflux disease, increased salivary secretion, excessive burping and belching, lip inflammation, gastrointestinal disorder, oral pain, abnormal contractions of muscles of the oesophagus, blockage in the stomach and intestine, stomach ulcer, retroperitoneal fibrosis, teeth that crack or break easily, swallowing difficulty, disorder of the salivary gland, haemorrhoids
- Skin: loss of skin colour, peeling skin, excessive body hair, nail shrinkage, excessive sweating
- General: general condition worsening, weight increase, redness and swelling at the injection site, cancer pain and bleeding, multiple organ failure
- Changes in blood tests: high blood sugar, high blood lipids, changes in blood clotting time, high blood cell counts, low or high protein level
- Other: frequent urination, blood in urine, neck pain, back pain, breast pain, muscle tightness or cramps, joint swelling, limb discomfort, muscle weakness, arthritis inflammation and pain

Rare side effects (affect 1 to 10 users in 10,000) and very rare side effects (affect less than 1 user in 10,000) include:

- acute liver failure, reactivation of previous hepatitis B virus
- lung inflammation (possible difficulty breathing)
- pancreas infection
- muscle breakdown
- loss sense of smell

- sun allergy
- widespread blood clotting and bleeding
- disease affecting the white matter of the brain
- serious illness with blistering of the skin, mouth and genitals
- terminal ileitis (an inflammatory condition of the terminal portion of the ileum)

If you experience any of the side effects or if you notice any side effects not listed in this leaflet, please tell your doctor.

If any of the side effects get serious, stop taking TS-ONE[®] OD Tablet and tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TS-ONE[®] OD Tablet

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Keep away from moisture after opening the package.

Do not use TS-ONE[®] OD Tablet after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

TS-ONE[®] OD Tablet 20: an orally disintegrating, pale blue-green tablet with a white disc inset centrally in one face, having a characteristic odor.

TS-ONE[®] OD Tablet 25: an orally disintegrating, pale orange tablet with a white disc inset centrally in one face, having a characteristic odor.

- Ingredients

- Active ingredients

The active substances are Tegafur, Gimeracil and Oteracil potassium.

TS-ONE[®] OD Tablet 20 contains 20 mg Tegafur, 5.8 mg Gimeracil, and 19.6 mg Oteracil potassium (equivalent to 15.8 mg of oteracil free acid)

TS-ONE[®] OD Tablet 25 contains 25 mg Tegafur, 7.25 mg gimeracil, and 24.5 mg Oteracil potassium (equivalent to 19.7 mg of oteracil free acid)

- Inactive ingredients

Lactose hydrate
Microcrystalline cellulose
Crospovidone
Partly pregelatinized starch
Aspartame
Magnesium stearate
Hydroxypropylcellulose
Flavour (Peach Micron ZE-2798)
Yellow ferric oxide
Blue No. 2 aluminium lake (*for TS-ONE[®] OD Tablet 20 only*)
Yellow No. 5 aluminium lake (*for TS-ONE[®] OD Tablet 25 only*)

- MAL number:

TS-ONE[®] OD Tablet 20:
MAL19071004AZ

TS-ONE[®] OD Tablet 25:
MAL19071005AZ

Manufacturer

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Product Registration Holder

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