

Package leaflet: Information for the user

Teysuno 15 mg/4.35 mg/11.8 mg hard capsules tegafur/gimeracil/oteracil

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 get any side effects, talk to your doctor. This includes any possible any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Teysuno is and what it is used for
2. What you need to know before you take Teysuno
3. How to take Teysuno
4. Possible side effects
5. How to store Teysuno
6. Contents of the pack and other information

1. What is Teysuno and what is it used for

Teysuno contains the active substances tegafur, gimeracil and oteracil.

Teysuno belongs to the fluoropyrimidine class of medicines known as “antineoplastic agents” which stop the growth of cancer cells.

Teysuno is prescribed by doctors for:

- The treatment of adults with advanced stomach (gastric) cancer and is taken with cisplatin, another anti-cancer medicine.
- The treatment of cancer of the large intestines and rectum which has spread (metastasized) and where it is not possible to continue with another fluoropyrimidine (anti-cancer treatments from the same group of medicines as Teysuno) due to side effects on the skin of hands or feet (hand-foot syndrome) or on the heart. In these patients, Teysuno is used alone or in combination with other anticancer medicines.

2. What you need to know before you take Teysuno

Do not take Teysuno if you:

- are allergic to tegafur, gimeracil, oteracil or any of the other ingredients of this medicine (listed in section 6).
- are taking other fluoropyrimidine anti-cancer medicine such as fluorouracil and capecitabine, or have had severe and unexpected reactions to fluoropyrimidines
- know that you do not have any activity of the enzyme dihydropyrimidine dehydrogenase (DPD) (complete DPD deficiency)
- are pregnant or breast-feeding
- have severe blood disorders
- have kidney disease requiring dialysis
- are being treated now or have been treated in the last 4 weeks with brivudine as part of herpes zoster (chickenpox or shingles) therapy.

Warnings and precautions

Talk to your doctor before taking Teysuno if you have:

- blood disorders
- kidney disease
- stomach and/or bowel problems such as pain, diarrhoea, vomiting and dehydration
- eye disorders, such as “dry eye” or increased tearing
- a current or previous infection of the liver with the hepatitis B virus, since your doctor may want to monitor you more closely
- a partial deficiency in the activity of the enzyme dihydropyrimidine dehydrogenase (DPD)
- a family member who has partial or complete deficiency of the enzyme dihydropyrimidine dehydrogenase (DPD)

DPD deficiency: DPD deficiency is a genetic condition that is not usually associated with health problems unless you receive certain medicines. If you have DPD deficiency and take Teysuno, you are at an increased risk of severe side effects (listed under section 4 Possible side effects). It is recommended to test you for DPD deficiency before start of treatment. If you have no activity of the enzyme you should not take Teysuno. If you have a reduced enzyme activity (partial deficiency) your doctor might prescribe a reduced dose. If you have negative test results for DPD deficiency, severe and life-threatening side effects may still occur.

If you develop lack of energy, confusion, sleepiness, seizures or impaired consciousness, please contact your doctor immediately.

Children and adolescents

Teysono is not recommended for children under 18 years of age.

Other medicines and Teysuno

Tell your doctor if you are taking, have recently taken or might take any other medicines.

You must not take brivudine (an anti-viral medicine for the treatment of shingles or chickenpox) at the same time as Teysuno treatment (including during any rest periods when you are not taking any Teysuno capsules). If you have taken brivudine you must wait for at least 4 weeks after stopping brivudine before starting to take Teysuno. See also section “Do not take Teysuno”.

Also, you need to be particularly careful if you are taking any of the following:

- other fluoropyrimidine based medicines such as the anti-fungal flucytosine. Teysuno cannot be substituted for other oral fluoropyrimidine medicine.
- inhibitors of the enzyme CYP2A6 which activates Teysuno 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
- certain antibiotics called nitroimidazoles, such as metronidazole (used to treat bacterial infections) and misonidazole (used in cancer treatment)
- methotrexate (a medicine used to treat cancer, rheumatoid arthritis, and severe psoriasis)
- clozapine (a medicine used to treat schizophrenia)
- cimetidine (a medicine used to treat stomach ulcers and heartburn)

Teysono with food and drink

Teysono should be taken at least one hour before or one hour after a meal.

Pregnancy and breast-feeding

Before starting treatment, you must tell your doctor or pharmacist if you are pregnant, if you think you are pregnant, or if you intend to become pregnant. You must not take Teysuno if you are pregnant or think you might be.

Men must use contraceptive measures during and up to 3 months after treatment with Teysuno.

Women must use contraceptive measures during and up to 6 months after treatment with Teysuno. If you become pregnant during this time, you must tell your doctor. You must not breastfeed if you are taking Teysuno. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Use caution when driving or operating a machine, as Teysuno may make you tired, nauseous or have blurred vision. If you have any doubts talk to your doctor.

Teysuno 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.

3. How to take Teysuno

Always take Teysuno exactly as your doctor has told you. You should check with your doctor if you are not sure.

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 Teysuno 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.

Teysuno capsules should be swallowed with water at least 1 hour before or 1 hour after a meal. Teysuno must be taken twice daily (morning and evening).

For stomach cancer:

Teysuno capsules are usually taken for 21 days followed by a 7 day rest period (when no capsules are taken). This 28 day period is one treatment cycle. The cycles are repeated.

Teysuno will be given with another anti-cancer medicine called cisplatin. Cisplatin will be stopped after 6 treatment cycles. Teysuno can be continued after stopping cisplatin.

For cancer of the large intestines or rectum that has spread:

Teysuno capsules are usually taken for 14 days followed by a 7 day rest period (when no capsules are taken). This 21 day period is one treatment cycle. The cycles are repeated.

Teysuno can be given with other anti-cancer medicines (cisplatin, oxaliplatin, irinotecan or bevacizumab), which will depend on your treatment.

If you take more Teysuno than you should

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

If you forget to take Teysuno

Do not take the missed dose at all and do not take a double dose to make up for a forgotten dose. Instead, continue your regular dosing schedule and check with your doctor.

If you stop taking Teysuno

There are no side effects caused by stopping treatment with Teysuno. In case you are using blood thinning or anti-seizure medicines, stopping Teysuno might require that your doctor adjusts the dose of your medicines.

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

4. Possible side effects

Like all medicines, Teysuno 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.

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

- **Diarrhoea, nausea, vomiting, constipation**
 - o If you experience diarrhoea more than 4 times a day or in the middle of the night, or if you experience sore mouth accompanied by diarrhoea, **stop taking Teysuno and contact your doctor immediately.**
 - o If you experience diarrhoea, avoid high-fibre, fatty and spicy foods.
 - o 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.
 - o If you experience nausea and vomit a dose of medication, make sure you tell your doctor. Do not replace the dose that has been vomited.
 - o If you vomit more than two times in 24 hours, **stop taking Teysuno and contact your doctor immediately.**
 - o 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
 - o You may have symptoms such as cold hands and feet, looking pale, light-headedness, fatigue, breathlessness.
 - o 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
 - o You may have symptoms such as fever, chills, coughing, sore throat.
 - o If you have fever of 38.5^o C or higher, **stop taking Teysuno and contact your doctor immediately.**
 - o 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
 - o If you have bleeding of the skin, mouth (caused by brushing teeth), nose, respiratory tract, stomach, gut, etc., **stop taking Teysuno and contact your doctor immediately.**
 - o 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
 - o You may become dehydrated if you do not eat and/or drink enough water.
 - o If you become dehydrated you may have symptoms such as dry mouth, weakness, dry skin, dizziness, cramping
 - o Try to eat frequent small meals. Avoid fatty and strong-smelling food. Even if you do not feel hungry, continue to eat as much as you can to maintain good nutrition.
 - o 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 (may affect 1 to 10 in 100 people) include:

- **Nerve:** headache, dizziness, sleeplessness, changes in taste
- **Eye:** eye problems, increased or decreased tearing discomfort, vision problems, serious illness

with blistering of the eyes, wearing away of the surface “skin” of the eye (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 blood tests which show the way the liver is working,
- **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, changes in blood tests which show the way the kidney is working, kidney impairment and failure
- **Other:** chills, weight decrease, swelling in specific areas and muscle bone pain

Uncommon side effects (may affect 1 to 10 in 1,000 people) 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, 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 heart beat, 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 (may affect 1 to 10 in 10,000 people) and very rare side effects (may affect less than 1 in 10,000 people) include:

- acute liver failure
- pancreas infection
- muscle breakdown
- loss of 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
- recurrence (reactivation) of hepatitis B infection when you have had hepatitis B in the past (a liver infection)
- high blood ammonia levels

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 Teysuno and tell your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Teysuno

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the outer carton and blister after EXP. The expiry date refers to the last day of the 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 Teysuno contains

- The active substances are tegafur, gimeracil and oteracil.
Each hard capsule contains 15 mg tegafur, 4.35 mg gimeracil, and 11.8 mg oteracil (as monopotassium).
- The other ingredients are:

Capsule contents: lactose monohydrate, magnesium stearate

Capsule shell: gelatin, red iron oxide (E172), titanium dioxide (E171), sodium lauryl sulphate, talc

Ink: red iron oxide (E172), yellow iron oxide (E172), Indigo carmine (E132), carnauba wax, bleached shellac, glyceryl monooleate

What Teysuno looks like and contents of the pack

The hard capsules have a white body and opaque brown cap imprinted "TC448" in grey. They are provided in blisters containing 14 capsules each.

Each pack contains 42 capsules.

Marketing Authorisation Holder

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