

Drug Information Sheet("Kusuri-no-Shiori")

Internal

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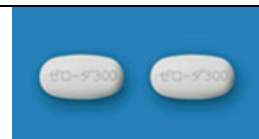
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:XELODA Tablet 300

Active ingredient:Capecitabine

Dosage form:white tablet (major axis: approx. 13.4 mm, minor axis: approx. 7.1 mm, thickness: approx. 4.8 mm)

Imprint or print on wrapping:ゼローダ 300



Effects of this medicine

This medicine is metabolized by enzymes which abound in malignant tumors, acts on the tumors effectively, and interferes with growth of the tumors.

It is usually used for treatment of inoperable or recurrent breast cancer, colorectal cancer and gastric cancer.

The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
- If you have or had been receiving treatment with combined ingredient of tegafur, gimeracil and oteracil potassium within the last 7 days.
- If you have a history of coronary artery disease.
- If you have myelosuppression, or gastrointestinal ulcer/bleeding, renal disorder, hepatic disorder.
- If you are pregnant, possibly pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- For treatment of inoperable or recurrent breast cancer : Take the medicine according to any of the following procedures.
 - In general, according to the body surface area, take 3 to 5 tablets (900 to 1,500 mg of the active ingredient) at a time, twice a day, within 30 minutes after breakfast and dinner. Take the medicine for consecutive 21 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.
 - In general, according to the body surface area, take 5 to 8 tablets (1,500 to 2,400 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 14 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.
 - When given concomitantly with lapatinib tosylate hydrate, in general, according to the body surface area, take 4 to 7 tablets (1,200 to 2,100 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 14 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.
- For adjuvant chemotherapy for colorectal cancer : Take the medicine according to any of the following procedures.
 - In general, according to the body surface area, take 5 to 8 tablets (1,500 to 2,400 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 14 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.
 - When given concomitantly with oxaliplatin, according to the body surface area, take 4 to 7 tablets (1,200 to 2,100 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 14 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.
- For treatment of advanced or recurrent colorectal cancer, which is not amenable to curative resection : It is used along with other anti-malignant tumor medicines. In general, according to the body surface area, take 3 to 7 tablets (900 to 2,100 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 14 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.
- For adjuvant chemotherapy for rectum cancer treated with concurrent radiotherapy : In general, according to the body surface area, take 3 to 5 tablets (900 to 1,500 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 5 days and after that discontinue taking the medicine for 2 days, and repeat this dosing schedule.

For treatment of gastric cancer : It is used along with a platinum-based regimen. In general, according to the body surface area, take 4 to 7 tablets (1,200 to 2,100 mg) at a time, twice a day, within 30 minutes after breakfast and dinner, however, the dosage may be decreased according to the conditions. Take the medicine for consecutive 14 days and after that discontinue taking the medicine for 7 days, and repeat this dosing schedule.

In any case, strictly follow the instructions.

- If you miss a dose, skip the missed dose and continue your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist. The medicine may cause serious nausea, vomiting, diarrhea, mucositis, gastrointestinal stimulus or bleeding, or myelosuppression.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- The medicine may decrease the immune system, and is likely to cause infections such as cold. Take enough care, such as to avoid being in crowd, to wash the hands and to gargle after returning home.
- The medicine may cause bleeding tendency. Take enough care of symptoms such as nose bleeding, gum bleeding and bruise.
- If you are a female patient who has a possibility of pregnancy, or you are a male patient whose partner has a possibility of pregnancy, avoid pregnancy while taking this medicine and for a certain period of time after its discontinuation.
- When you visit another medical institution or buy other medicine at a pharmacy, make sure to tell the doctor/pharmacist that you are taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include neurotoxicity (peripheral sensory neuropathy, peripheral motor neuropathy, etc.), nausea, loss of appetite, fatigue, vomiting, injection site reaction, pigmentation disorder, abnormal taste, diarrhea, stomatitis and hand-foot syndrome. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- thirst, weight loss, dizziness on standing up, dizziness, easy fatigability, general weakness, cramp [dehydration]
- sensitivity or insensitivity in the palms of the hands or the soles of the feet, redness/blister/skin sore of hands/feet [hand-foot syndrome]
- edema, cold sweat, breathing difficulty, shortness of breath, easy fatigability, weight gain, constrictive chest pain, sense of being compressed strongly on the chest, jaw pain, left arm pain [cardiac disorder]
- easy fatigability, general dullness, weakness, loss of appetite, nausea [liver disorder]
- yellowness in the white of the eye, yellowness in the skin, dark urine, itchy body [jaundice]
- edema, decreased urinary volume, general dullness [renal disorder]
- fever, chills, sore throat, nose/gum bleeding, shortness of breath, bruise, prolonged bleeding, dull headache, palpitation [myelosuppression]
- white coat appearing on oral membrane/tongue and becoming rough, oral pain by eating/drinking, swallowing difficulty, oral wound/swelling, loss of appetite [stomatitis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store at room temperature (1 to 30 degrees Celsius) away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.