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

Internal
Revised: 02/2025

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:FOLINATE TABLETS 25mg「OHARA」

Active ingredient: Folinate
Dosage form:white tablet, diameter: 8.1 mm, thickness: 3.4 mm
Imprint or print on wrapping:ホリナート 25 mg「オーハラ」, 食事の前後1時間をさけて服用する, Folinate25 mg「OHARA」

Effects of this medicine

This medicine is a reduced folic acid formulation with no antitumor effect in itself. However, it enhances the antitumor effects of the anti-cancer medicine tegafur/uracil when used concomitantly with the combined medicine (folinate/tegafur/uracil therapy). This therapy is expected to relieve symptoms through reduction in the size of cancer (tumor).
It is usually used for colorectal 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 bone marrow suppression (decrease in white blood cell count, etc.), diarrhea, infections, renal disorder, gastrointestinal ulcer/bleeding, diabetes mellitus or varicella (chickenpox).
If you have or have a history of liver disorder or heart disease.
If you are currently receiving radiotherapy.
If you have been treated with anti-cancer medicines before.
If you are taking a tegafur/gimeracil/oteracil potassium combined medicine or have taken this combined medicine within the last 7 days.
・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))
・In general, for adults, take 1 tablet (25 mg as folinate) at a time with a tegafur/uracil combined medicine 3 times a day (about every 8 hours), avoiding 1 hour before and after meals, for 28 consecutive days (4 weeks), and then stop taking the medicines for 7 days (1 week). This is counted as one cycle and is repeated. Strictly follow the instructions.
・You should never take this medicine with a tegafur/gimeracil/oteracil potassium combined medicine. You should also not take this medicine if you have stopped taking a tegafur/gimeracil/oteracil potassium combined medicine within the last 7 days.
・If you miss a dose, skip the missed dose and follow 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.
・Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

・During the treatment, laboratory tests (hematological, liver and renal function tests) are performed regularly to detect asymptomatic adverse reactions as early as possible. Be sure to keep your visiting schedule.
・If you have a possibility of becoming pregnant, use an adequate contraception while you are taking this medicine and for 6 months after you finish taking this medicine.
・Men should use a barrier method (condom) of contraception while you are taking this medicine and for 3 months after you finish taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, stomatitis, loss of appetite, nausea, vomiting, taste abnormality, general malaise, pigmentation, rash, itch and abdominal pain. 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.

- ・prolonged bleeding, general malaise, sore throat, fever [blood disorder such as bone marrow suppression and hemolytic anemia]
- ・yellow discoloration of the skin, general malaise, yellow discoloration of the white of eyes, loss of appetite [severe hepatic dysfunction]
- ・diarrhea, severe abdominal pain [serious enterocolitis]
- ・light headedness, forgetfulness, difficulty speaking [psychoneurotic disorder including leukoencephalopathy]
- ・olfactory disturbance [anosmia]
- ・breathing difficulty, fever, dry cough [interstitial pneumonia]

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 away from light, heat 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.

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