

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

Injection

Revised: 09/2023

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:LEVOFOLINATE FOR I.V. DRIP INFUSION 100 「OHARA」

Active ingredient:Calcium levofolinate hydrate

Dosage form:injection

Imprint or print on wrapping:



Effects of this medicine

This medicine belongs to the group called active folic acid preparation. This medicine enhances the suppressive effect of

the cancer cell proliferation antitumor effect by concomitant use with fluorouracil.

It is usually used for the purpose of enhancing the effect of fluorouracil for the treatment of gastric cancer (which is inoperable or recurrent), colorectal cancer, small intestinal cancer and pancreatic cancer not amenable to curative resection and advanced/recurrent 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: fever, generalized dullness, diarrhea, varicella (chickenpox) or other infectious disease, ascites, pleural effusion, heart disease or its history, poor general condition, liver disorder, renal disorder, liver metastasis or gastrointestinal ulcer or bleeding.

If you are receiving the combination preparation of tegafur/gimeracil/oteracil potassium or have discontinued it within 7 days.

If you are receiving radiotherapy.

If you have previously received treatment with chemotherapy.

- If you are 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, inject this medicine by intravenous infusion over 2 hours at a time.

- Dosing intervals depend on concomitant medicines and the symptoms/condition of the patient. Ask the doctor about the treatment span.

Precautions while taking this medicine

- If you have decreased bone-marrow function, infection or bleeding may tend to occur. However, it is difficult to find out these symptoms so that you should receive clinical examination (blood test, liver/renal function test, etc.) regularly (frequently during early treatment period, in particular) for earlier detection.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, loss of appetite, nausea/vomiting, stomatitis, fever, rash, taste abnormality, abdominal pain, epigastric pain, thirst, constipation, gingivitis, cheilitis/angular stomatitis, glossitis, abdominal bloating, melena and heartburn. 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.

- persistent muddy or watery stool [severe diarrhea]

- chills, fever, bleeding tendency [bone marrow suppression]

- severe abdominal pain, diarrhea [serious enterocolitis]

- respiratory distress, generalized hot flashes, hives [shock, anaphylaxis]

- general dullness, loss of appetite, yellowing of the skin or whites of the eyes [liver dysfunction, jaundice]

- decreased urine output, edema of limbs, general dullness [acute renal disorder]

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

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

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