

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

Injection

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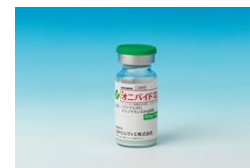
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic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

Brand name:Onivyde I.V. Infusion 43mg

Active ingredient:Irinotecan hydrochloride hydrate

Dosage form:injection

Imprint or print on wrapping:



Effects of this medicine

This medicine inhibits enzyme involved in DNA synthesis of cancer cells and suppresses the proliferation of cancer cells.

It is usually used to treat unresectable pancreatic cancer that has progressed after cancer chemotherapy.

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 myelosuppression, infectious diseases, diarrhea, intestinal tract paralysis/intestinal obstruction, interstitial lung disease or pulmonary fibrosis, ascites/pleural effusion or jaundice.
- 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, inject this medicine by intravenous infusion over 90 minutes once a day and then it is discontinued for 13 days. This dosing schedule is regarded as 1 course and repeated.
- Consult with your doctor about the duration of treatment.

Precautions while taking this medicine

- The medicinal effects may be affected by some kinds of foods or drinks. Do not take grapefruit juice during the treatment because it may intensify the medicinal effects. Refrain from taking foods containing St. John's wort (hypericum perforatum) because they may diminish the medicinal effects.
- Frequent blood test should be performed because serious adverse drug reactions such as myelodepression and severe diarrhea may occur. Chest imaging test should be also periodically performed because interstitial lung disease may occur.
- Female patients with a possibility of pregnancy or male patients whose partner has a possibility of pregnancy should avoid pregnancy while using this medicine and for a certain period of time after its completion.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, vomiting, stomatitis, constipation, abdominal pain, asthenia, fever, decreased appetite, taste abnormality, alopecia and decreased body weight. 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.

- fever, bleeding tendency, anemic symptoms [myelosuppression]
- abdominal pain, watery stool, muddy loose stool [diarrhea]
- fever, chills, general malaise [infection]
- general malaise, loss of appetite, yellowing of the white of eyes and skin [liver dysfunction, jaundice]
- consciousness disorder, breathing difficulty, hives/itching, swelling of eyelids/lips/tongue [infusion reaction]

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.