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

Internal
Revised: 04/2024

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:TEMODAL Capsules 20mg

Active ingredient: Temozolomide
Dosage form:white opaque capsule, major axis: 17.8 mm, minor axis: 6.1 mm
Imprint or print on wrapping:TEMODAL, 20mg

Effects of this medicine

This medicine suppresses tumor cell growth and shows anticancer effect.
It is usually used to treat malignant glioma and recurrent or refractory Ewing's sarcoma.

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: bleeding tendency, renal disorder, liver disorder, infectious diseases or varicella.
・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 newly-diagnosed malignant glioma: Concomitantly with radiotherapy, in general, for adults, take 75 mg/m^2 of the active ingredient (per body surface area) at a time, once a day, for 42 consecutive days, and withdraw the medication for 4 weeks. After the above-described course, in administration of Temodal alone, take 150 mg/m^2 of the active ingredient at a time, once a day, for 5 consecutive days, and withdraw the medication for 23 days. This 28-day is defined as one course, and the dosage may be increased to 200 mg/m^2 at a time, in the next course.
For treatment of recurrent malignant glioma: In general, for adults, take 150 mg/m^2 of the active ingredient (per body surface area) at a time, once a day, for 5 consecutive days, and withdraw the medication for 23 days. This 28-day is defined as one course, and the dosage may be increased to 200 mg/m^2 at a time, in the next course.
For treatment of recurrent or refractory Ewing's sarcoma: Concomitantly with irinotecan, in general, take 100 mg/m^2 of the active ingredient at a time, once a day, for 5 consecutive days, and withdraw the medication for 16 days or longer. This is defined as one course and this treatment course is repeated. The dosage may be decreased according to the condition.
This preparation contains 20 mg of the active ingredient in a capsule. In any case, strictly follow the instructions.
・Never open the capsule, and take it with an adequate amount of water without chewing. Wash the medicine off if the content in the capsule is attached to the body.
・It is recommended to take this medicine on an empty stomach to enhance its absorptivity. Taking this medicine after meals will decrease its absorptivity.
・You may develop vomiting after taking this medicine. If you threw up, do not take this medicine again on the day regardless of whether you threw up the capsule or not.
・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

・Follow the instructions of your doctor and receive a blood test regularly.
・If female patients have a possibility of becoming pregnant, avoid pregnancy in an appropriate way while using this medicine and for 6 months after completion of the treatment.
・Male patients should use a barrier method (condom) for contraception while using this medicine and for 3 months after completion of the treatment.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include malaise, headache, anemia, nausea, vomiting, loss of appetite, constipation, diarrhea and fatigue. 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.

・anemic symptom, fever, bleeding tendency [myelosuppression]
・fever, cough, phlegm [Pneumocystis pneumonia, infectious diseases]
・fever, dry cough, breathing difficulty [interstitial pneumonia]
・headache, vomiting, hemiplegia [cerebral bleeding]
・breathing difficulty, hives, swelling around the eyes or lips [anaphylaxis]
・general malaise, loss of appetite, yellow discoloration of skin and/or conjunctiva [liver dysfunction, jaundice]
・fever, erythema (red rash) with dropsical swelling in the center, bloodshot eyes [toxic epidermal necrolysis, Stevens-Johnson syndrome]

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.

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