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

Internal

Published: 12/2016

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: ISOSORBIDE ORAL SOLUTION 70% "CEO"

Active ingredient: Isosorbide

Dosage form: colorless to pale yellowish brown solution Print on wrapping:イソソルビド内用液 70%「CEO」

Effects of this medicine

This medicine mobilize fluid in the tissues into the blood and suppresses water reabsorption in the kidney. It consequently lowers intracranial pressure and/or intraocular pressure.

It is usually used for lowering intracranial pressure in case of brain tumor or brain hypertension resulting from head injury, diuresis in case of kidney/ureteral stone, lowering intraocular pressure in glaucoma, and treatment of Meniere's disease.

Before 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.
- If you have acute intracranial hematoma.
- ·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))
- For lowering brain pressure/intraocular pressure or diuresis: In general, for adults, take 70 to 140 mL (49 to 98 g of the active ingredient) a day in 2 or 3 divided doses. The dosage should be adjusted according to your disease and symptoms.

For Meniere's disease: Standard daily dose is 1.5 to 2.0 mL/kg of the body weight. In general, for adults, take 90 to 120 mL (63 to 84 g) at a time, 3 times a day after meals. The dosage should be adjusted according to your symptoms

If it is hard to drink, mix it with an equal amount of cold water and take it. Strictly follow the instructions.

- · If you miss a dose, take the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should not 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, diarrhea, vomiting, rash and erythema. 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.

•rash, respiratory distress, decreased blood pressure, palpitation [shock, anaphylaxis]

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 direct sunlight, heat and moisture.
- It may discolor in some environments, which does not affect the medicinal effects.
- Open it just before taking and discard the remained solution.

For healthcare professional use only

For further information, talk to your doctor or pharmacist.