

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

Internal

Revised: 02/2021

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:**Orfadin Capsules 5mg  
**Active ingredient:**Nitisinone  
**Dosage form:**white capsule, No. 3 capsule  
**Print on wrapping:**



## Effects of this medicine

This medicine inhibits 4-hydroxyphenylpyruvate dioxygenase in the tyrosine degradation pathway to restrict the generation of toxic metabolites and alleviates diseases.

It is usually used to treat hypertyrosinemia type I.

## 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 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, take 1 mg/kg of the active ingredient per day, in 2 divided doses. The dosage may be adjusted according to the symptoms. If it is not effective enough, the dosage may be increased up to 2 mg/kg per day. This preparation contains 5 mg of the active ingredient in a capsule. Strictly follow the instructions.
- Take this medicine as soon as possible after taking it out of the bottle, and close the cap of the bottle and store it.
- 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 follow your regular dosing schedule.
- 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

- Strictly follow dietary therapy instructed by your doctor.
- You may have vision disorder by taking this medicine. Pay close attention when you operate dangerous machinery, such as driving a car.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include exfoliative dermatitis, erythematous eruption and itch. 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.**

- blurred vision, bloodshot eyes, foreign-body sensation, sensitive to light, eye pain, itch of eyelid [eye disorder]
- nose/gum/subcutaneous bleeding, sore throat, fever [thrombocytopenia, leukopenia, granulocytopenia]

**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 reach of children. Avoid freezing and store it at 2 to 8 degrees Celsius (refrigerator).
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution how to discard.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.