

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

Internal

Published: 04/2020

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:** TIGASON Capsule 25**Active ingredient:** Etretinate**Dosage form:** pale red-brown/pale red-brown capsule (major axis: approx. 17.6mm)**Print on wrapping:** チガソン 25mg**Effects of this medicine**

This medicine makes abnormally cornified skin/oral mucosa easy to fall away and help reform skin surface/mucosa back to normal. It is usually used to treat serious psoriasis and ichthyosis.

**Before using this medicine, be sure to tell your doctor and pharmacist**

- If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.  
If you are a patient with hepatic/renal disorder or hypervitaminosis A.  
If you are predisposed to have hypertriglyceridemia. (For example, you have diabetes, obesity, alcoholism or lipid metabolism abnormality.)
- 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))
- In general, for adults, in order to induce a remission, take 40 to 50 mg of the active ingredient in 2 to 3 divided doses a day for 2 to 4 weeks. The maximum daily dosage is 75 mg of the active ingredient. After that, in order to maintain remission, take 10 to 30 mg of the active ingredient in 1 to 3 divided doses a day according to the patients symptoms.  
In general, for infants and children, in order to induce a remission, take 1.0 mg/kg of the active ingredient in 1 to 3 divided doses a day for 2 to 4 weeks. After that, in order to remain remission, take 0.6 to 0.8 mg/kg of the active ingredient in 1 to 3 divided doses a day according to the patients symptoms.  
The dosage may be adjusted according to the age, weight and symptoms in any case.  
1 capsule contains 25 mg of the active ingredient. Strictly follow the instructions of your doctor/pharmacist.
- Avoid taking this medicine with a great amount of milk or fatty food.
- If you miss a dose, . You should take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. DO NOT take a double dose to make up for the missed dose.
- 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**

- This medicine has possibility to cause fetal anomaly (teratogenesis) and has a higher incidence of side effects.  
Receive full explanation about side effects until you fully understand them.
- In using this medicine, receive full explanation about precautions mentioned below until you fully understand them.  
If you agree, sign the letter of consent.
- If you have possibility of pregnancy, you cannot take this medicine until 2 to 3 days after the start of your next menstruation. Also, you may receive a pregnancy test within 2 weeks before taking this medicine.
- If you have a possibility of pregnancy, make sure to avoid pregnancy during use and for at least 2 years after withdrawal of this medicine.
- A male patient must avoid pregnancy during use and for at least 6 months after withdrawal of this medicine.
- Blood donation is prohibited during use and for at least 2 years after withdrawal of this medicine.
- When you have joint/bone pain, contact your doctor immediately. Also, if you are supposed to take this medicine for a long period, you may have to take an X-ray examination, etc.
- This medicine may cause liver damage. For the early detection of the side effects, your liver function will be checked before and 1 month after starting this medication, and also every 3 months during use. Keep all appointments with your doctor/laboratories.
- Blood tests will be conducted to patients with hypertriglyceridemia who tend to have lipid metabolism abnormality.
- This medicine may cause hair loss, cheilitis, or desquamation (skin surface peeling off).

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include cheilitis, desquamation (scaly skin peeling off), dry mouth, thinning of the skin and pruritus . 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.**

- joint pain, sore red skin, red spots and breakable blisters all over the body, lassitude [toxic epidermal necrosis]
- rash and blister, joint pain, fever [erythema multiforme]
- angialgia, purple bruise, swelling [vasculitis]

**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. Ask the pharmacist or healthcare facility how to discard.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.