

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

Internal

Revised: 01/2021

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: Onetram Tablets 100mg

Active ingredient: Tramadol hydrochloride

Dosage form: white to grayish white tablet, diameter: 9.7 mm, thickness: 5.2 mm

Print on wrapping: フントラム錠 100mg, 134, 100, Onetram Tab. 100mg



Effects of this medicine

This medicine relieves severe pain by binding to opioid receptor and inhibiting reuptake of monoamine. It is usually used to treat cancer pain and chronic pain that is non-responsive to non-opioid analgesics.

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 intoxication caused by alcohol, sleeping pills, painkiller, opioid pain reliever or psychotropic drug, epilepsy with inadequate therapeutic management, renal disorder or liver disorder.
If you have used other drug(s) within the past 2 weeks.
- 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, for adults, take 1 to 3 tablets (100 to 300 mg of the active ingredient) at a time, once a day. The dosage may be adjusted according to the symptoms. The maximum daily dose is 4 tablets (400 mg). Strictly follow the instructions.
- Since this medicine is a sustained release preparation, it can not be used as a rescue dose, in case of sudden cancer pain exacerbation. If you need a rescue dose, take tramadol hydrochloride immediate release preparation.
- Since this medicine is a sustained release preparation, swallow the tablet without splitting, crushing or chewing.
- If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose. 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

- This medicine may cause sleepiness, dizziness or loss of consciousness. There have been cases reported that loss of consciousness resulted in car accidents. Avoid operating dangerous machinery, such as driving a car.
- Since alcohol drinking may intensify medicinal or medical effects and adverse reactions, avoid drinking during medication.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include constipation, nausea, vomiting, somnolence, dizziness, dry mouth and loss of appetite. 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.

- respiratory distress, wheezing (whistling breath), swelling around the eyes and lips [shock, anaphylaxis]
- breathing becomes shallow and fast, difficult to breathe, breathing difficulty [respiratory depression]
- sudden muscle contraction [convulsion]
- unable to stop using the medicine, sleeplessness, anxiety [dependence]
- loss of consciousness [unconsciousness]

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. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. If you dispose of unused medicines, ask the pharmacy and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.