

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

Internal

Revised: 02/2023

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 round tablet, diameter: 9.7 mm, thickness: 5.2 mm

**Imprint or print on wrapping:** ワントラム錠 100mg, 134, 徐放錠, 100, Onetram Tab.100mg, かまずに飲んでください



**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. However, it does not cure the disease itself.

**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: acute intoxication caused by alcohol, sleeping pills, painkiller, opioid pain reliever or psychotropic medicine, epilepsy with inadequate therapeutic management, renal dysfunction or liver dysfunction.  
If you have used other medicine(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.
- Try to take this medicine at around the same time each day.
- Since this medicine is a sustained release preparation, take tramadol hydrochloride immediate release preparation when you experience sudden exacerbation of cancer pain and need a rescue dose.
- 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. However, if you noticed it on and after the next day, 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. Symptoms such as constricted pupils, vomiting, cold sweat, dizziness, shortness of breath, cardiovascular collapse (shock state such as cold sweat, decreased blood pressure and pale face), convulsion, decrease in breathing and respiratory arrest may occur. If any of these symptoms occur, get immediate medical attention.
- Do not stop taking this medicine unless your doctor instructs you to do so.

**Precautions while taking this medicine**

- This medicine may cause symptoms such as nausea, vomiting and constipation. As a countermeasure, laxatives and antinausea preparations may be concomitantly administered.
- 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.
- The tablet may be excreted as white solids in the stool.

**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.**

- dyspnea, 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 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 dispose of the unused medicines, 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.