

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

Internal

Revised: 12/2023

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: TOARASET COMBINATION TABLETS 「OHARA」

Active ingredient: Tramadol hydrochloride
Acetaminophen

Dosage form: pale yellow tablet, major axis: 15.2 mm, minor axis: 6.4 mm, thickness: 5.1 mm

Imprint or print on wrapping: (Face)トアラセット配合錠「オーハラ」, トラマドール塩酸塩 37.5 mg, アセトアミノフェン 325 mg
(Back)TOARASET Combination Tab.「OHARA」



Effects of this medicine

This medicine shows analgesic effects by acting on the central nervous system.

It is usually used to treat chronic non-cancer pain and pain after tooth extraction, that are difficult to treat with non-opioid analgesics.

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 are a habitual heavy drinker.
- If you have acute intoxication with alcohol/hypnotics/analgesics/opioid analgesics or psychotropics.
- If you are within 14 days after stopping monoamine oxidase inhibitor medication (Selegiline Hydrochloride, Rasagiline Mesilate, Safinamide Mesilate) or within 1 week after stopping nalmefene hydrochloride.
- If you have epilepsy not adequately controlled by treatment, gastrointestinal ulcer, abnormality of the blood, liver disorder, renal disorder or cardiac function failure.
- If you have or have a history of aspirin asthma.
- 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 chronic non-cancer pain: In general, for adults, take 1 tablet at a time, 4 times a day. Wait at least 4 hours to take the next dose. The dosage may be adjusted according to the symptoms. However, the maximum dose should not exceed 2 tablets at a time, 8 tablets a day. If you have aspirin asthma or have had aspirin asthma, take only 1 tablet at a time. Avoid taking this medicine on an empty stomach.
- For pain after tooth extraction: In general, for adults, take 2 tablets at a time. Wait at least 4 hours to take an additional dose, and the maximum dose should not exceed 2 tablets at a time, 8 tablets a day. Avoid taking this medicine on an empty stomach.
- In any case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, wait at least 4 hours to take the next 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 drowsiness, dizziness or loss of consciousness. Avoid operating dangerous machinery, such as driving a car. There have been reports of cases in which loss of consciousness caused car accidents.
- For a long period administration, the liver function may be checked on a regular basis. In that case, take the test at the designated date and time.
- Drinking alcohol intensifies medicinal effects, and may result in respiratory depression and liver disorder. Pay close attention to avoid drinking alcohol while taking this medicine.
- If you are breastfeeding, avoid breastfeeding while using this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nausea, vomiting, somnolence, constipation and dizziness. 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.

- breathing difficulty, hives, semi-consciousness [shock, anaphylaxis]
- shallow and rapid breathing, breathing difficulty [respiratory depression]
- convulsion [convulsion]
- decreased consciousness, impaired mind, impaired judgment [loss of consciousness]
- unable to stop using this medicine when you attempted to discontinue [dependence]
- high fever (38 degrees or more), eye bloodshot, erosions of mouth/lips, facial/generalized redness [toxic epidermal necrolysis, muco-cutaneo-ocular syndrome, acute generalized exanthematous pustulosis]

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.
- Discard the remainder. Do not store them. If you do not know how to dispose, ask your pharmacy or medical institution on how to discard the remainder. Do not give it to others.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.

SIE③