

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

Internal

Revised: 11/2019

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:TrancolonP Tablets

Active ingredient:Mepenzolate bromide
Phenobarbital

Dosage form:white tablet, diameter: approx. 6.1 mm, thickness: approx. 3.0 mm

Print on wrapping:(Face)トランコロン P, house-mark, 配合錠, アステラス製薬, f464, トランコロン P 配合錠, (Back) トランコロン P 配合錠, f464, house mark, アステラス製薬, Trancolon P



Effects of this medicine

This medicine acts on the enteric nerves and exerts an antispasmodic effect, thus controlling abnormal intestinal movements together with a sedative effect.

It is usually used to improve symptoms of irritable colon, including abdominal pain, repeated diarrhea and constipation, etc.

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: angle closure glaucoma, impaired urination due to prostatic hypertrophy, a heart disorder or persistent constipation due to paralysis of the intestine.
- 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 2 tablets at a time, 3 times a day. The dosage may be adjusted according to the age or symptoms. Strictly follow the instructions.
- 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. 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, decreases in attention/concentration/reflexive movements and vision adjustment disorder such as feeling light dazzling or focus disorder. Avoid operating dangerous machinery such as driving a car.
- Alcohol intake may enhance the effect of this medicine. Do not drink alcohol while you are taking this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include vision adjustment disorder, dry mouth, constipation, nausea/vomiting, loss of appetite, impaired urination, dizziness, headache/dull headache and rash. 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.

- fever, erythema, blister/erosion [toxic epidermal necrolysis, oculomucocutaneous syndrome, erythroderma]
- rash, fever, swollen lymph nodes [hypersensitivity syndrome]
- inability to stop taking the medicine [drug dependence]
- sore throat, fever, general malaise [granulocytopenia, decreased platelets]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction]

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. Consult with your dispensing pharmacy or medical institution when you discard the medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.