

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

Internal

Revised: 02/2015

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:Emilace Tablets 3mg**

**Active ingredient:**Nemonapride

**Dosage form:**white tablet (diameter: 6.7mm, thickness: 3.4mm)

**Print on wrapping:**(Face) エミレース, house-mark, house-mark + 021, 3mg, (Back) エミレース, 3mg, house-mark



**Effects of this medicine**

This medicine acts on a transmitter (dopamine) in the brain and relieves anxiety, tension and excitement. It is used to stabilize the mental state.

It is usually used for the treatment of schizophrenia.

**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 become comatose.
- If you have Parkinson's disease.
- 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 3 to 12 tablets (9 to 36 mg of the active ingredient) per day, in divided portions, after meals. The dosage may be adjusted according to the patient's age and symptoms, and the daily dose may be increased up to a maximum of 20 tablets (60 mg). Strictly follow the instructions.
- If you miss a dose, do not take the missed dose. Skip the missed dose and continue 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**

- Taking this medicine may cause sleepiness, decreased attention or inability to react immediately. Do not operate dangerous machinery such as driving a car.
- Intake of alcohol may enhance the effect of this medicine. Refrain from drinking alcohol while taking the medicine.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include Parkinson's syndrome (tremor, muscle rigidity, salivation, etc.), dyskinesia (lispy voice, language disorder, eye rotation, difficulty with swallowing, etc.), akathisia (inability to sit still) 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.**

- spiking fever, tremor of the hands and legs, stiffness of the muscles [neuroleptic malignant syndrome]
- throat pain, headache, fever [agranulocytosis, decreased white blood cell]
- general weakness, loss of appetite, yellowing of the skin and the whites of the eye [hepatic function disorder, jaundice]
- difficulty with breathing, chest pain, varicose vein pain/hot feeling [pulmonary embolism, deep vein thrombosis]

**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 infants and children. Store away from direct sunlight, heat and humidity.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution how to discard.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.