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

Internal

Revised: 07/2016

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: NAUZELIN Dry Syrup 1%

Active ingredient:Domperidone Dosage form:white dry syrup

Print on wrapping:KH310 ナウゼリンドライシロップ

Effects of this medicine

This medicine suppresses activities of dopamine in the stomach and duodenum to improve gastrointestinal motility, and acts on CTZ (chemoreceptor trigger zone) involved in causing nausea to suppress nausea.

It is usually used to treat nausea caused by cold or periodic vomiting in children.

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: gastrointestinal bleeding, mechanical ileus, gastrointestinal perforation, prolactinoma, hepatic disorder, renal disorder, heart disease, dehydration or fever.
- · If you are pregnant, possible 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 children, take 0.1 to 0.2 g (1 to 2 mg of the active ingredient) per kilogram of the body weight daily, in three divided doses, before meals. Mix the medicine with water when you take it. The dosage may be adjusted according to the age, body weight or symptoms, however, the maximum daily dose is 3 g (30 mg). The maximum daily dose for children 6 years old or older is 0.1 g (1 mg) per kilogram of the body weight. Strictly follow the instructions
- If you miss a 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 and dizziness. Take care in driving a car or engaging in dangerous activities.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, extrapyramidal disorder (muscle stiffness, tremor of limbs, etc.), sleepiness, rash and gynecomastia in children. 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.

- dizziness, orthostatic dizziness, cold sweat, facial pallor [shock]
- •breathing difficulty, hives, swelling around eyes and mouth [anaphylaxis]
- •tremor of limbs, muscle stiffness, twist or cramp in neck, upward rotation of eyes [extrapyramidal symptoms]
- ·decreased consciousness, sudden muscle contraction [consciousness disorder, convulsion]
- general malaise, loss of appetite, yellowing in skin and white of eyes [hepatic dysfunction, jaundice]

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.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.