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

Internal

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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: TRIMEBUTINE MALEATE FINE GRANULES 20% 「OHARA」

Active ingredient:Trimebutine maleate

Dosage form: white to faintly yellowish white fine granule

Print on wrapping:トリメブチンマレイン酸塩 20%「オーハラ」, 100 mg/包 (0.5g), OH-264,

Trimebutine Maleate 20% OHARA

Effects of this medicine

This medicine adjusts decreased or abnormally increased gastric or bowel motility by directly acting on gastrointestinal smooth muscles.

It is usually used to treat gastrointestinal symptoms (abdominal pain, nausea, belching and abdominal bloating) caused by chronic gastritis and irritable bowel syndrome.

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 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 gastrointestinal symptoms caused by chronic gastritis: In general, for adults, take 0.5g (100 mg of the active ingredient) at a time, 3 times a day. The dosage may be adjusted according to age or symptoms.
- <u>For irritable bowel syndrome:</u> In general, for adults, take 0.5 to 1g (100 to 200 mg) at a time, 3 times a day. In any case, 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include constipation, diarrhea, dry mouth, rash and itch. 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.

• general malaise, loss of appetite, yellow discoloration of the skin and the white of eyes [liver 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

- ${}^{\textstyle \bullet} \text{Keep}$ out of the reach of children. Store away from direct sunlight, heat and moisture.
- ${}^{\textstyle \bullet} \textsc{Discard}$ the remainder. Do not store them.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.

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