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: MOVICOL

Active ingredient: Macrogol 4000

Sodium chloride Sodium bicarbonate Potassium chloride

Dosage form: white powder

Print on wrapping:慢性便秘症治療薬 モビコール配合内用剤 MOVICOL 6.9g



Effects of this medicine

This medicine promotes the defecation in a dose-dependent manner by maintaining moisture in the intestinal tract owing to the potent osmotic action of the main active ingredient Macrogol 4000.

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 or are suspected of having intestinal obstruction, intestinal perforation or inflammatory intestinal disease (ulcerative colitis, Crohn's disease, toxic megacolon, etc.).
- · 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))
- •Dissolve 1 sachet of this medicine in one-third glass of water (about 60 mL).

In general, for infants aged 2 to 6 years, start with 1 sachet at a time, once a day. Then the dosage will be adjusted to 1 to 3 times a day, according to the symptoms. The maximum daily dose is 4 sachets (2 sachets at a time). The dose should be increased by an increment not greater than 1 sachet a day with an interval of at least 2 days. In general, for children aged 7 to 11 years, start with 2 sachets at a time, once a day. Then the dosage will be adjusted to 1 to 3 times a day, according to the symptoms. The maximum daily dose is 4 sachets (2 sachets at a time). The dose should be increased by an increment not greater than 1 sachet a day with an interval of at least 2 days.

In general, for adults and children aged 12 years or over, start with 2 sachets at a time, once a day. Then the dosage will be adjusted to 1 to 3 times a day, according to the symptoms. The maximum daily dose is 6 sachets (4 sachets at a time). The dose should be increased by an increment not greater than 2 sachets a day with an interval of at least 2 days.

In any case, strictly follow the instructions.

- ·If you miss a dose, you may take the missed dose anytime. However, you should not 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 diarrhea, abdominal pain, rash, erythema, angioedema (swelling of face, respiratory distress), hives, 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.

• hives, respiratory distress, facial edema [shock, anaphylaxis]

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.
- This medicine should be dissolved at the time of taking the medicine. If you are storing the medicinal solution for any reason, store in the refrigerator and use it as soon as possible.
- ·Discard the remainder. Do not store them.

For healthcare professional use only	/	/	

For further information, talk to your doctor or pharmacist.