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

External

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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: FLUTICASONE PROPIONATE NASAL SOLUTION 50mcg "CEO" 56 sprays

Active ingredient: Fluticasone propionate

Dosage form: nasal solution of metered-dose system, color of container: white (body),

clear green (cap)

Print on wrapping:フルチカゾンプロピオン酸エステル点鼻液 50 μg「CEO」56 噴霧用



Effects of this medicine

This medicine suppresses inflammation of the nasal mucosa to reduce the severity and frequency of nasal symptoms (sneeze, nasal discharge, nasal congestion).

It is usually used to treat allergic/vasomotor rhinitis. It is not used for the acute relief of nasal symptoms.

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 infections, systemic mycosis, nasopharynx infections, or recurrent nasal bleeding.
- ·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, spray 1 puff (50 mcg of the active ingredient) at a time into both nasal cavities, twice a day. The dose may be adjusted according to your symptoms. However, the maximum daily dose is 8 puffs (400 mcg). Strictly follow the instructions.
- •Read the instruction leaflet "how to use nasal metered-dose inhaler" attached to the product and the carrying bag thoroughly before using this medicine.
- ·Shake the bottle before use.
- Never use a pin to prick the tip of the nozzle. It will damage the nozzle and the spray would not work.
- If you miss a dose, use the missed dose as soon as possible. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. You should not use two doses at one time.
- · If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop using 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 rash, edema, nasal symptoms (irritating sensation, pain, feeling of dryness) and nasal bleeding. 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.

•respiratory distress, generalized flushing, angioedema, hives [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.
- •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.