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

External

Revised: 10/2024

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: BECLOMETASONE NASAL SOLUTION 50mcg "CEO"

Active ingredient:Beclometasone dipropionate

 $\textbf{Dosage form:} suspension \ agent \ of \ metered-dose \ system, \ (cap) \ lavender$

Imprint or print on wrapping:ベクロメタゾン点鼻液 50 μ g「CEO」

Microsophi Microsophi

Effects of this medicine

This medicine is synthetic adrenal corticosteroid. It 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.

The following patients may need to be careful when 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 or foods.
- If you have infection, systemic mycoses, tuberculous disease, hypertension, diabetic mellitus or recurrent epistaxis.
- · 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))
- ·Before use, blow your nose to help open the nasal passages, and shake the bottle well.

<u>For adults</u>: In general, spray 1 puff (100 mcg of the active ingredient) at a time into both nasal cavities, 4 times a day. The dose may be adjusted according to your age, body weight and symptoms. However, the maximum daily dose is 16 puffs.

<u>For children</u>: In general, spray 1 puff (100 mcg of the active ingredient) at a time into both nasal cavities, twice a day. The dose may be adjusted according to your age, body weight and symptoms. However, the maximum daily dose is 8 puffs.

In any case, strictly follow the instructions.

- •Read the instruction leaflet "how to use nasal metered-dose inhaler" attached to the product thoroughly before using this medicine.
- Shake the bottle well 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 erythema, itch, edema, hives, nasal symptoms (irritating sensation, itch, feeling of dryness, discomfort feeling), nasal bleeding and infections. 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.

- sensitive to light, foggy vision, eye pain [high fluid pressure in the eye]
- severe eye pain, acute reduction in visual acuity, nausea [glaucoma]

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. If you do not know how to discard, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.

For healthcare professional use only

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