

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

Internal

Revised: 04/2020

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: Vesicare OD Tablets 5mg

Active ingredient: Solifenacin succinate

Dosage form: pale yellow orally-disintegrating tablet, diameter: approx. 7.5 mm, thickness: approx. 4.0 mm

Print on wrapping:(Face) ベシケア OD5mg, ベシケア OD, 口腔内崩壊錠, 5mg, アステラス製薬, (Back) Vesicare OD, ベシケア OD, 5mg, 過活動膀胱治療剤, house-mark, アステラス製薬



Effects of this medicine

This medicine acts on the muscarinic receptors in the bladder in an opposing manner to control excessive involuntary bladder contraction, and thus allows the bladder to retain urine.

It is usually used to treat urinary urgency, frequent urination and urge urinary incontinence associated with overactive bladder.

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: urinary retention, angle closure glaucoma, obstruction and paralytic ileus of pylorus, duodenum or intestinal tract, gastric atony or intestinal atony, myasthenia gravis, heart disease or liver disorder.
- 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, take 1 tablet (5 mg of the active ingredient) at a time, once a day. The dosage may be adjusted according to the age or symptoms. However, the maximum daily dose should not exceed 2 tablets (10 mg). Strictly follow the instructions.
- Take the tablet with water or lukewarm water in the same way as you usually take tablets. Since the tablet promptly dissolves in saliva, you may place it on your tongue, moisten with saliva, crush it with your tongue and swallow it together with saliva.
- This medicine contains irritating ingredients. Do not chew the tablet.
- Do not take the tablet without water when you are lying down.
- If you miss a dose, skip the missed dose and follow your regular dosing schedule from the next day. 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 abnormality of the eyes such as foggy vision, focus disorder or sleep-like state of consciousness. Pay close attention when you perform dangerous operations such as working at heights or driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dry mouth and constipation. 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, decreased blood pressure [shock, anaphylaxis]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction]
- inability to urinate, difficulty to urinate [urinary retention]
- shortness of breath, chest pain, dizziness [QT prolongation, ventricular tachycardia, atrioventricular block, sick sinus syndrome, severe bradycardia]
- persistent constipation, abdominal bloating, abdominal pain [paralytic ileus]
- impaired mind, loss of sense of time, place, etc., seeing thing or hearing sound that does not really exist [hallucination/delirium]
- nausea, eye pain accompanied by headache, reduced visual acuity [acute glaucoma attack]

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 reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.