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

Internal

Revised: 08/2024

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:**Pollakisu 1mg Tablets

Active ingredient: Oxybutynin hydrochloride

**Dosage form:**white tablet, diameter: 8.1 mm, thickness: 3.4 mm

Imprint or print on wrapping:ポラキス錠 1, 1mg

#### Effects of this medicine

This medicine increases bladder capacity and pressure threshold for micturition by suppressing hypertonicity of bladder through neurotropic effects (antimuscarinic effects) and direct effects on bladder smooth muscles (calcium antagonistic effects).

It is usually used to treat frequent urination/urinary urgency/urinary incontinence in neurogenic bladder/unstable

## 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 urination difficulty/urinary retention, glaucoma, heart disease, paralytic ileus (intestinal obstruction), debility, intestinal atony, myasthenia gravis, prostatic hypertrophy, hyperthyroidism, ulcerative colitis or liver/renal disease.

If you are in a hot environment.

If you are elderly with Parkinson's syndrome or dementia symptoms.

- 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 2 to 3 tablets (2 to 3 mg of the active ingredient) at a time, 3 times a day. The dosage may be adjusted according to the age or symptoms. 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

• This medicine may cause vision adjustment disorder or drowsiness. Pay attention when operating dangerous machinery, such as driving a car.

#### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include dry mouth, urination difficulty, constipation, diarrhea, gastrointestinal disorder and rash. 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.

- •nose bleeding, gum bleeding, purpura [decreased platelets]
- •significant constipation, abdominal bloating, abdominal pain [paralytic ileus]
- •difficulty to urinate [urinary retention]

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.

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For further information, talk to your doctor or pharmacist.