

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

Internal

Revised: 10/2021

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: Betanis Tablets 50mg

**Active ingredient:** Mirabegron

**Dosage form:** yellow tablet (major axis: approx. 12.1 mm, minor axis: approx. 6.1 mm, thickness: approx. 5.2 mm)

**Print on wrapping:** (Face) ベタニス 50mg, ベタニス, 50mg, アステラス製薬, (Back) Betanis 50mg, ベタニス, 50mg, 過活動膀胱治療剤, house-mark, アステラス製薬



## Effects of this medicine

This medicine improves urge to urinate, pollakiuria and urge incontinence by regulating a neurotransmitter in the bladder and relaxing the bladder muscles.

It is usually used for the treatment of urge to urinate, pollakiuria and urge incontinence due to 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 a heart disease or liver dysfunction.
- If you are pregnant, possibly 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 (50 mg of the active ingredient) at a time, once a day, after a meal. You may start with a lower dose depending on your symptoms. Strictly follow the instructions.
- Do not split or crunch the tablets. Take it with a glass of water or lukewarm water.
- If you miss a dose, do not take the missed dose on the day, but follow your regular dosing schedule from the next day on. 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

### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include constipation and dry mouth. 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.**

- inability to urinate, urination difficulty [urinary retention]
- headache, dull headache (heaviness of head), dizziness [hypertension]

**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. Consult with your dispensing pharmacy or medical institution when you discard the medicine.

### For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.