

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

Internal

Revised: 05/2019

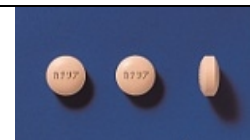
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

## Brand name: CANALIA Combination Tablets

**Active ingredient:** Teneeligliptin hydrobromide hydrate  
Canagliflozin hydrate

**Dosage form:** pale orange tablet, diameter 8.6 mm, thickness 4.5 mm

**Imprint or print on wrapping:** (Face) カナリア配合錠, カナリア, 糖尿病用薬, 1日1回服用  
(Back) カナリア配合錠, Canalia, 糖尿病用薬, テネリグリプチンとして20mg, カナグリフロジンとして100mg



## Effects of this medicine

This medicine improves glycemic control through enhancing insulin secretion by inhibiting degradation of incretin, which is a hormone regulating blood glucose levels, and reduces blood glucose levels through excretion of excess glucose into urine by inhibiting renal glucose reabsorption.

It is usually used to treat type 2 diabetes mellitus.

## 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 ketosis, diabetic coma or precoma stage, type 1 diabetes mellitus, infection, in pre/post operative period, or trauma.
- 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 at a time, once a day before or after breakfast. Strictly follow the instructions.
- If you miss a dose, skip the missed dose and continue 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

- Strictly follow the instructions on dietary/exercise therapy.
- This medicine may cause hypoglycemic symptoms. Take care in working at heights, driving a car or operating machinery requiring alertness.
- If any of hypoglycemic symptoms occur, take a sufficient amount of sugar (table sugar, glucose, soft drinks, etc.). If you concomitantly take  $\alpha$ -glucosidase inhibitor (a medicine that delays absorption of sugar), take glucose in case of any hypoglycemic symptoms.
- This medicine may cause dehydration. Try to keep yourself well hydrated.
- This medicine may cause ketoacidosis even without hyperglycemia. If any of symptoms of ketoacidosis occur, consult with your doctor immediately.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include frequent urination, vulvovaginal candidiasis, constipation and thirst. 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.**

- cold sweat, hungry feeling, shaky limbs [hypoglycemia]
- thirst, general malaise, dizziness [dehydration]
- nausea/vomiting, deep and heavy breathing, decreased consciousness/judgment [ketoacidosis]
- chills, fever, flank/back pain [pyelonephritis, sepsis]
- fever, swelling/pain/redness of perineum [necrotising fasciitis of perineum (Fournier's gangrene)]
- severe constipation, stomach inflation, continued abdominal pain [intestinal obstruction]
- general malaise, loss of appetite, yellowing of the skin or the whites of the eyes [hepatic function disorder]
- dry cough, respiratory distress, fever [interstitial pneumonia]

- rash with blister [pemphigoid]
- severe pain in the upper abdomen, back pain, nausea [acute pancreatitis]

**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.