620006946 Revised: 06/2011

Information is based on approvals granted in Japan. In some cases, the approved details may vary in countries other than Japan.

In deciding to use a medicine, the risk (side effects) of taking the medicine must be weighed against the benefit (effects) it will do. The patient's cooperation is indispensable here.

# **Brand name: SUPACAL TABLETS 40mg**

Active ingredient: Trepibutone

Dosage form: white to yellowish white tablet ( : 7.6 mm, thickness: 2.9 mm)

Printings on wrapping: スパカール 40mg, OH-251, 40mg, Supacal 40mg

#### Effects of this medicine

This medicine promotes secretion of the bile and pancreatic juice, and accelerates flaccidity of the smooth muscle in the gastrointestinal tract (sphincter of hepatopancreatic ampulla etc.) to lower internal pressure of the gallbladder and bile duct. It improves the symptoms of the bile duct and pancreatic disease.

It is usually used for improvement of cramp and bile secretion associated with cholelithiasis, cholecystitis, cholangitis, dyskinesia of the biliary tract or postcholecystectomy syndrome, or pain and gastrointestinal symptoms associated with chronic pancreatitis.

#### Before using this medicine, tell your doctor/pharmacist

- If you ever experienced any allergic reaction (itch, rash etc.) to any medicine.
- · If you are pregnant or breastfeeding.
- If you are using any other prescription or nonprescription (OTC) medicine. (It is important to reduce the risk of drug interactions.)

# Dosage regimen (proper use of this medicine)

· Your dosage regimen is:

:order of your doctor

- General dosage regimen: For adults, take 1 tablet (40 mg of the active ingredient) at a time, 3 times daily, immediately after meal. However, the dosage may be adjusted according to the diseases, age or symptoms. Strictly follow the instructions of your doctor/pharmacist.
- Missed dose: Take a dose as soon as possible when you remember that you missed a dose. However,
  if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule.
  DO NOT take double doses to make up for the missed dose.
- Overdose: If you took too much of the medicine (more than ordered), check with your doctor/pharmacist.
- Others: Do not stop taking the medicine without the instructions of your doctor.

### Precautions while using this medicine

#### Side effects of this medicine

Common side effects are reported as below. If any of them occurs, check with your doctor/pharmacist: nausea, constipation, abdominal bloating, diarrhea, rash, itch, etc.

In rare cases, symptoms described below may be the sign of side effects indicated in brackets [ ]. If they occur, stop taking your medicine and check with your doctor immediately.

No pertinent entries.

Other side effects not listed here may occur. Check with your doctor/pharmacist if you have any worrisome symptom.

# Storage and other information

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

For doctor use only: Day

Month

Year

For further information, ask your doctor/pharmacist. Japanese package insert information (for medical professionals) is available on the website of Pharmaceuticals and Medical Devices Agency.