DESCRIPTION

1. Composition
Each dark red and light yellow brown hard capsule contains 40 mg of flopropione. It also contains FD&C Yellow No. 6 (Sunset Yellow-FCF), microcrystalline cellulose, FD&C Blue No.1 (Brilliant Blue-FCF), FD&C Red No.3 (Erythrosine), gelatin, talc, corn starch and sodium lauryl sulfate as inactive ingredients.

2. Product description

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Dosage form and identification code</th>
<th>Appearance</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>COSPANON Capsules 40mg</td>
<td>Capsule</td>
<td>Length (mm) 15.9</td>
<td>Weight (mg) 231</td>
</tr>
</tbody>
</table>

INDICATIONS
Antispasmodic effect resulting from the following diseases:
Hepatobiliary disorders: biliary dyskinesia, cholelithiasis, cholecystitis, cholangitis and post-cholecystectomy syndrome
Pancreatic disease: pancreatitis
Urinary calculus

DOSAGE AND ADMINISTRATION
The usual adult dosage for oral use is 1 to 2 capsules (40-80 mg of flopropione) three times daily after meals.

PRECAUTIONS
1. Careful Administration (COSPANON should be administered with care in the following patients.)
Patients with a history of hypersensitivity reaction to any ingredients of COSPANON.

2. Adverse Reactions
Adverse reactions were reported in 194 of 4,273 patients (4.54%). (At the end of the investigation for incidence of adverse reactions)

<table>
<thead>
<tr>
<th>Gastrointestinal</th>
<th>5% &gt; ≥ 0.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea/vomiting, heart burn and feeling of enlarged abdomen</td>
<td></td>
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<tr>
<td>Hypersensitivity*</td>
<td>Rash</td>
</tr>
</tbody>
</table>

Note) In the event of such symptoms, treatment should be discontinued.

3. Use in the Elderly
Since the elderly often have a physiological hypofunction, it is advisable to take measures, such as reduction in dosage under careful supervision.

4. Use during Pregnancy, Delivery or Lactation
The safety of COSPANON in pregnant women has not been established (no clinical experience).

5. Pediatric Use
Safety in children has not been established (insufficient clinical experience).

6. Precautions concerning Use
Caution in handing over drug
For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the package prior to use. [It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, causing perforation and resulting in serious complications such as mediastinitis.]

PHARMACOKINETICS
Six Capsules of COSPANON Capsules 40 mg were administered to 12 healthy male volunteers at a single dose of 240 mg (note) of flopropione and the changes in the plasma concentration of unchanged flopropione was determined. The peak plasma concentration was about 9 μg/mL at 1 hr after administration. Thereafter, the plasma concentration declined gradu-
ally, and then flopropione almost completely disappeared from the plasma within 24 hr of administration.

**PHYSICOCHEMISTRY**

Nonproprietary name: Flopropione (JAN, INN)

Chemical name: 1-(2,4,6-Trihydroxyphenyl) propan-1-one

Molecular formula: C₉H₁₀O₄

Molecular weight: 182.17

Structural formula:

![Structural formula of Flopropione](image)

Description:
Flopropione occurs as a white to pale yellow-brown, crystalline powder. It is very soluble in N, N-dimethylformamide, freely soluble in methanol and in ethanol (99.5), practically insoluble in water.

Melting point: 177-181°C

**PACKAGING**

COSPANON Capsules 40 mg:
Boxes of 100 and 1,000 in press-through packages, and bottles of 500

**REFERENCES**


**REQUEST FOR LITERATURE AND PRODUCT INFORMATION SHOULD BE MADE TO:**
Customer Information Service
Free Dial: 0120-419-497
Eisai Co., Ltd.

Manufactured and marketed by:
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