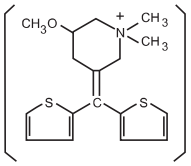
ANTISPASMODIC AGENT

SESDEN®

Mitsubishi Tanabe Pharma

(COMPOSITION AND DESCRIPTION)

- Generic name : Timepidium bromide
- Chemical name : 1,1-Dimethyl-5methoxy-3-(dithien-2-ylmethylene) piperidinium bromide monohydrate.



Br- · H_2O

$C_{17}H_{22}BrNOS_2 \cdot H_2O$:418,42

- It is odorless white crystal or crystalline powder having a bitter taste.
- It is very soluble in methanol and in glacial acetic acid, freely soluble in chloroform, sparingly soluble in water, slightly soluble in absolute acetone and practically insoluble in ether.
- It melts about 197℃, with decomposition.

Product's names	Content of Timepidium bromide	Description of the product
SESDEN® Capsule	30 mg per capsule	Size 5 capsule White TA Orange

(ACTION)

(PHARMACOLOGICAL ACTIONS)

Timepidium bromide has an action at receptor of acetylcholine in the peripheral parasympathetic nerves. It relieves the spasm of smooth muscle and inhibits the secretion of gastric juice and hydrochloric acid and peptic ulcer formation. The antisialic and mydriatic actions were weak.

1. Antispasmodic action:
   Timepidium bromide relieves the spasm of the smooth muscle of the upper and lower gastrointestinal tracts, biliary tract, urinary tract and urinary bladder.
   - Timepidium bromide given intravenously to rats showed the action to inhibit the gastrospasm induced by vagal stimulation about 3 times stronger than that by atropine sulfate and about 5 times stronger than that by hyoscine-N-butylbromide.
   - At a dose of 2 mg/kg p.o. in cats, timepidium bromide inhibited maximum 60% of the spontaneous movements of the stomach at 30- 60 minutes after the drug administration, which lasted for about 2 hours.
     At a dose of 5 - 40 μg/kg i.v., it also inhibited the spontaneous movements of the jejunum, Oddi's sphincter and urinary bladder and the spasm of the large intestine elicited by the pelvic nerve stimulation.
   - At a dose of 0.5 mg/kg i.v. in dogs, timepidium bromide inhibited the spontaneous movements of the duodenum and Oddi's sphincter, and reduced the internal pressure of the gallbladder. At a dose of 0,1 mg/kg i.v., it also inhibited the spontaneous movements of the urinary tract.
2. Anti secretory actions of gastric juice and free hydrochloric acid, anti-ulcer action:
   - Gastric fistula rats : at a dose of 0,2 mg/kg i.v in gastric fistula rats, timepidium bromide inhibited the secretions of gastric juice and free hydrochloric acid stronger than those by hyoscine-N-butylbromide.

(INDICATIONS)

1. Pain due to spasm of smooth muscle caused by the following diseases :
   Gastric, gastric and duodenal ulcer, intestinitis, gallbladder and bile-duct diseases, and lithangiuria.
2. Pain caused by pancreatitis.

(ADMINISTRATION AND DOSAGE)

For adults, usually one capsule (30 mg Tipepidium bromide) three times daily by oral administration.
The dosage may be increased or decreased depending upon the age and symptoms of a patient.

(PRECAUTION)

1. It Should not be given to patients with glaucoma, dysuria caused by prostatomegaly, severe cardiac diseases, paralytic ileus or patients who had experience of hypersensitivity to this drug.
2. It should be carefully given to patients with the following diseases :
   - Prostatomegaly.
   - Hyperthyroidism, congestive cardiac failure, arrhytmia, idiopathic ulcerative colitis (toxic giant-colon may occur) or patients working under high temperature surrounding.
3. Adverse reaction:
   1) Eye :
      Photophobia may occur infrequently. Visual disturbances may occur rarely.

2) Psychoneurologic system :
Dizziness, headache, vertigo and the like may occur infrequently. Heaviness of head, sleepiness and the like may occur rarely.
3) Digestive system :
Thirst, dry mouth, constipation, and the like may occur infrequently. Anorexia, soft stool, feeling enlarged of abdomen, nausea, vomiting, flatulence, and the like may occur rarely.
4) Cardiovascular system :
Palpitation may occur infrequently.
5) Hypersensitivity :
Hypersensitivity symptoms such as eruption and the like may occur infrequently, in such case, the medication should be discontinued.
6) Urogenital system :
Dysuria may occur rarely.
7) Others :
Facial hot, malaise, flushing and lassitude may occur rarely.

4. Drug Interaction :
The action of SESDEN® capsule may be strengthened by the concomitant use with the following drugs : Anticholinergic agents (such as tricyclic antidepressants, phenothiazine derivatives, antihistamines, etc.) and monoamine oxidase (MAO) inhibitors.
5. Attention should be paid to the urinary examinations such as urobilinogen test, since the urine may be colored to reddish by the metabolites of SESDEN® capsule.
6. Careful attention to patients received SESDEN® capsule should be paid in the operation of dangerous machines such as automobile driving, since visual disturbances and sleepiness way occur.
7. Timepidium bromide should be used in pregnant women or in women who may possibly be pregnant, only if the expected therapeutics benefits outweigh the possible risks associated with treatment. (The safety of the drug in pregnant women has not been established).
8. Lactating mothers should not receive the drug. If use of the drug is judged to be essential, breast feeding should be discontinued during treatment. (The safety of the drug in lactating mothers has not been established).
9. Since elderly patients tend to show thirst, dysuria, constipation, etc. caused by the anticholinergic action, Timepidium bromide should be carefully administered.
10. The safety of Timepidium bromide in children has not been established (a small number of clinical experience).

(CAUTIONS ON HANDLING)

STORAGE : Store in a tight and light resistant container at below 30 °C.

(PRESENTATION)

Box of 10 Blister sheets of 10 capsules

Reg. No. DKL7825202101A1

ON DOCTORS PRESCRIPTION ONLY
HARUS DENGAN RESEP DOKTER

Under license from
Mitsubishi Tanabe Pharma Corporation
Osaka, Japan

Manufactured by
PT Mitsubishi Tanabe Pharma Indonesia
Bandung, Indonesia