

SPASMINE®
200 mg Capsules

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about SPASMINE

Each SPASMINE slow release capsule for oral administration contains 200 mg mebeverine hydrochloride.

Other ingredients: colloidal anhydrous silica, povidone, ethyl cellulose, titanium dioxide, purified talc.

Mebeverine is a musculotropic antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract, biliary tract and genitourinary tract. Mebeverine relieves spasm without affecting normal gut motility.

SPASMINE is indicated in the following conditions:

- Symptomatic relief of abdominal pain, cramps, bowel disturbances (diarrhea or constipation), and intestinal discomfort related to irritable bowel syndrome
- Treatment of gastrointestinal spasm secondary to organic diseases
- Treatment of abdominal pain and spasm of the biliary tract and of the genitourinary tract including dysmenorrhea

The way to take SPASMINE

Take SPASMINE as directed.

The usual recommended dose is one capsule of 200 mg, twice daily with liquid, preferably before meals.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in case of hypersensitivity to any of the components.

Precautions

- This drug must be used with caution in case of hepatic or renal disease.
- Inform your doctor before using this medication in case of pregnancy or lactation. Safe use in pregnancy and lactation has not been established.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

No clinically relevant interactions with mebeverine were observed.

Adverse reactions

This drug is usually well tolerated. Nausea, headache and allergic reactions have been rarely reported.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

SPASMINE, mebeverine HCl 200 mg SR, pack of 30 capsules

Issue date: 06/2008

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