SPASMOBROM®

SPASMOBROM® 20 mg - coated tablets

Pipethanate ethobromide

PHARMACOTHERAPEUTIC CATEGORY

Anticholinergic and antispasmodic drug.

THERAPEUTIC INDICATIONS

Spastic states and increased gastrointestinal pathway motility; painful spastic states and altered motility of biliary and urinary ways; premedications and endoscopy and radiology tests.

CONTRAINDICATIONS

- Glaucoma.
- Prostatic hypertrophy or other causes of obstructive uropathy.
- Paralytic ileus and obstructive pathologies of the gastrointestinal tract.
- Severe ulcerous colitis and toxic megacolon.
- Hypersensitivity to the active substance or to any of the excipients.
- Generally contraindicated during pregnancy (See special precautions).

PRECAUTIONS FOR USE

No special precaution are required.

INTERACTIONS

The effects of anticholinergic preparations are amplified by the contextual administration of substances belonging to different therapeutic categories which also exert an anticholinergic effect such as antihistaminic drugs, butyrophenones, phenothiazidic drugs, tricyclic antidepressants and amantadine. As a consequence, these drugs should not be taken contextually with SPASMOBROM.

SPECIAL WARNINGS

The product contains lactose and therefore may be contraindicated for patients with galactose intolerance, Lapp lactase deficiency or glucose/galactose malabsorption.

The product contains saccharose and may therefore be contraindicated for patients with fructose intolerance, sucrase-isomaltase deficiency or glucose/galactose malabsorption.

Pregnancy and lactation. In pregnant women and during the earliest infant stages, the product must be administered in case of real need under the doctor's direct control.

DOSAGE, WHEN AND HOW TO ADMINISTRATE

- Unless otherwise prescribed by the treating physician, the recommended posology is as follows
- Coated tablets: 1-2 tablets, 2-4 times a day.
- The product is intended only for use by adults.

OVERDOSE

Experience with deliberate overdose is very limited.

As in all overdose cases, treatment should be symptomatic and include generic supporting measures. No specific antidote is available.

In case of accidental intake of medicinal product overdose to inform immediately the doctor or direct to the near hospital.

UNDESIRABLE EFFECTS

At therapeutic doses the product has not caused any atropine-like effects.

Rarely mild adverse reactions may occur which are typical of anticholinergic drugs (such as dry fauces and accommodation disorders): however these adverse reactions completely disappear without any consequences with dose reduction or suspension of the medication.

Gastrointestinal disorders Rare (>1/10.000 to <1/1000)	Dryness of the fauces
Visual disorders Rare (>1/10.000 to <1/1000)	Visual disorders

EXPIRATION DATE AND STORAGE

Check the expiration date printed on the case.

CAUTION: do not use the drug after the expiration date indicated on the case.

The expiration date refers to the product properly stored in its intact packaging.

No particular precaution is provided for storing the product.

Keep out of the reach of children.

COMPOSITION

SPASMOBROM 20 mg coated tablets

Each coated tablet contains:

Active principle

Pipethanate ethobromide 20 mg

Excipients

Lactose, corn starch, microgranular cellulose, talc, magnesium stearate, precipitated silica, saccharose

PHARMACEUTICAL FORM AND CONTENT

Coated tablets. Case with 30 tablets (20 mg each)

MARKETING AUTHORISATION HOLDER

ABC Farmaceutici S.p.A.

ABC International Division - Corso Vittorio Emanuele II, 72 - 10121 Turin - Italy

MANUFACTURE AND FINAL CONTROLS

ABC Farmaceutici S.p.A. - Canton Moretti, 29 - 10090 San Bernardo d'Ivrea (TO) - Italy

ABC INTERNATIONAL PHARMA