SPASMOBROM®

10 mg/ml injectable solution 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
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
- Injectable solution: 1-2 vials a day for intramuscular or intravenous.

The product is intended only for use by adults.

If you have any doubt about the use of the medicinal product, ask your doctor or pharmacist.

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.

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)	Accommodation 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 10 mg/1 ml injectable solution
Each vial contains:
Active ingredient:
Pipethanate ethobromide 10 mg
Excipients
Macrogol 300, benzyl alcohol, water for injection.

PHARMACEUTICAL FORM AND CONTENT
Injectable solution: case with 6 vials (10 mg/ml each)

MARKETING AUTHORISATION HOLDER
ABC International Pharma S.r.l.
Corso Stati Uniti, 61
10121 Turin - Italy

MANUFACTURE AND FINAL CONTROLS
Special Product's Line S.p.A.
Via Campobello, 15 - 00040 Pomezia (Italy)

Approved by the Ministry of Health in January 2010.