

SPASFON® ACINO SWITZERLAND

Composition:

Spasfon® active ingredients are phloroglucinal & trimethylphloroglucinal. Each Spasfon® Tablet coated tablet contains 80 mg phloroglucinal hydrate + 80 mg trimethylphloroglucinal;

Each Spasfon® Lyoc-80 oral lyophilisate contains 80 mg phloroglucinal hydrate;

Each Spasfon® Lyoc-160 oral lyophilisate contains 160 mg phloroglucinal hydrate;

Each Spasfon® Ampoule ampoule contains 40 mg phloroglucinal hydrate + 0.04 mg trimethylphloroglucinal in 4 mL for injection;

Each Spasfon® Suppository suppository contains 150 mg phloroglucinal hydrate + 150 mg trimethylphloroglucinal.

Indications and dosage:

Spasfon® is musculotropic antispasmodic, it relieves smooth muscle spasm & pain.

Spasfon® is indicated for:

- (1) symptomatic treatment of pain related to functional disorders of digestive tract & bile ducts
- (2) treatment of acute spasmodic painful disorders of urinary tract & renal colic
- (3) symptomatic treatment of acute pain in gynaecology
- (4) adjuvant treatment of contractions during pregnancy (Spasfon® Tablet, Spasfon® Lyoc-80/160, Spasfon® Suppository).

Spasfon® Tablet is given as 6 coated tablets per 24 hours;

Spasfon® Lyoc-80 as oral lyophilisate dissolved in water or dissolve under the tongue in adults as 2 oral lyophilisates at time of indication & repeated if severe pain and in children as 1 oral lyophilisate twice daily;

Spasfon® Lyoc-160 as oral lyophilisate dissolved in water or dissolve under the tongue in adults as 1 oral lyophilisate at time of indication & repeated if severe pain at an interval of at least 2 hours & maximally 3 oral lyophilisates/day.

Spasfon® Lyoc-160 is not suitable for children;

Spasfon® Ampoule at an initial dose of 1-3 ampoules per 24 hours by intravenous or intramuscular injection + possible maintenance dose of Spasfon tablets (6/24 hours) or suppositories (3/24 hours);

Spasfon® Suppository as 3 suppositories per 24 hours.

Contraindications:

Hypersensitivity to any of the ingredients.

Precautions:

Spasfon® should not be used concomitantly with potent analgesics such as morphine or its derivatives.

Pregnancy / lactation:

Only use if absolutely necessary during pregnancy; not recommended during breastfeeding.

Undesirable effects:

Skin, subcutaneous & allergic reactions, including rash, rarely urticaria, exceptional angioedema, hypotension, anaphylactic shock.

Interactions:

No interactions with other drugs are documented for Spasfon® but phloroglucinal solutions for injection should not be mixed in the same syringe with noramidopyrine due to risk of venous thrombosis (Spasfon® ampoule).

Presentation:

Spasfon® Tablet: packs containing 20, 30 or 50 coated tablets in blisters (PVC/Aluminium);

Spasfon® Lyoc-80: packs containing 10, 16 or 20 oral lyophilisates in blisters (PVC/Aluminium);

Spasfon® Lyoc-160: packs containing 5 or 10 oral lyophilisates in blisters (PVC/TE/PVDC/Aluminium) and sachets (PET/Aluminium/PE) containing 5 or 10 oral lyophilisates in blisters (PVC/TE/PVDC/Aluminium);

Spasfon® Ampoule: packs of 6, 12, 18 or 60 4 mL ampoules (glass);

Spasfon® Suppository: packs containing 10 or 100 suppositories in blisters (PVC Opaque).

Since indications, dosage forms and strengths may vary from country to country, please consult your local prescribing information. Full prescribing information, details and literature references are available on request.

Latest update of information: October 2008 (Spasfon® Tablet); October 2008 (Spasfon® Lyoc-80); April 2011 (Spasfon® Lyoc-160); March 2009 (Spasfon® Ampoule & Spasfon® Suppository).