Spasfon®

phloroglucinol

IDENTIFICATION OF MEDICINE

Trade name of the medicinal product :
SPASFON, solution for injection in ampoule.

Qualitative and quantitative composition :
Hydrated phloroglucinol ..... 40,00 mg
corresponding amount
of anhydrous phloroglucinol .....31,12 mg
Trimethylphloroglucinol ..... 0,04 mg
Excipients : sodium chloride, water for injections per ampoule.

Pharmaceutical form :
Solution for injection - pack of 6 ampoules.

Parmaco-therapeutic classification :
MUSCULOTROPIC ANTISPASMODIC
(A : digestive system and metabolism)
(G : genitourinary system)

Name and address of distributor and manufacturer :
Laboratoire L. LAFON - 19, avenue du Professeur Cadiot
B.P. 22 - 94701 MAISONS-ALFORT (FRANCE)

WHEN SHOULD THIS MEDICINE BE USED

(Therapeutic indications)
This medicine is intended to be used for the treatment of spasmodic pain arising from the intestine, biliary tract, bladder and uterus.

BEWARE !

When should this medicine not be used :
(Contraindications)
This medicine MUST NOT BE TAKEN in case of allergy to any of its constituents.
IF IN DOUBT, IT IS ESSENTIAL TO SEEK THE ADVICE OF YOUR DOCTOR OR YOUR PHARMACIST.

Precautions :
IF IN DOUBT, DO NOT HESITATE TO SEEK THE ADVICE OF YOUR DOCTOR OR YOUR PHARMACIST.

Drug interactions and other forms of interaction :
Phloroglucinol solution for injection must not be mixed in the same syringe with noramidopyrine because of physico-chemical incompatibility (risk of thrombophlebitis).
IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU SHOULD ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY ANOTHER TREATMENT THAT YOU MAY BE TAKING.

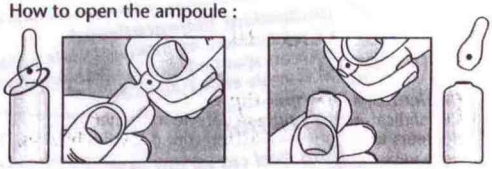
Pregnancy - Breast feeding :
This medicine should be taken during pregnancy only if necessary. Women should not take this medicine during breast feeding.
AS A MATTER OF GENERAL PRINCIPLE, YOU SHOULD ALWAYS SEEK THE ADVICE OF YOUR DOCTOR OR PHARMACIST BEFORE TAKING ANY MEDICINE IF YOU ARE PREGNANT OR BREAST FEEDING.

HOW TO USE THIS MEDICINE

Dosage :
Initial treatment : 1 to 3 ampoules per 24 hours by intravenous or intramuscular injection.
Maintenance treatment : Tablets or suppositories should be used following initial treatment, at the dosage of 6 tablets or 3 suppositories per 24 hours.

Method and route of administration :
By intravenous or intramuscular injection.

How to open the ampoule :



UNDESIRABLE AND TROUBLESOME EFFECTS

(Adverse effects)
IN COMMON WITH ALL ACTIVE SUBSTANCES, THIS MEDICINE MAY CAUSE TROUBLESOME EFFECTS OF VARYING DEGREES IN CERTAIN INDIVIDUALS :
- apparently allergic reactions, very rare but sometimes severe, have been reported : rash, urticaria, angioneurotic edema, hypotension - possibly to the point of shock.
TELL YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER UNDESIRABLE AND TROUBLESOME EFFECT NOT MENTIONED IN THIS PACKAGE INSERT INFORMATION.

STORAGE

Do not exceed the expiry date shown on the outer packaging.

Special storage precautions :
This medicine must be stored away from light.

DATE OF REVIEW OF PACKAGE INSERT INFORMATION

January 2001.