

IDENTIFICATION OF MEDICINE

Trade name of the medicinal product : SPASFON-LYOC 80 mg, oral lyophilisate.

Qualtitative and quantitative composition:

Hydrated phloroglucinol 80,00 mg corresponding amount of anhydrous phloroglucinol 62,25 mg Excipients: dextran 70, mannitol per oral lyophilisate.

Pharmaceutical form :

Oral lyophilisate - pack of 10.

Pharmaco-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.

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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:

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Drug interactions and other interactions :

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 FFFDING.

HOW TO USE THIS MEDICINE

Dosage:

The usual dose in adults is 2 oral lyophilisates, to be taken at the time of an attack and to be repeated in case of severe spasms.

Children: 1 oral lyophilisate twice a day.

Method and route of administration:

Adults: oral lyophilisates should be dissolved in a glass of water or allowed to melt under the tongue to obtain a faster effect.

Children: oral lyophilisates should be dissolved in a glass of water.

UNDESIRABLE AND TROUBLESOME EFFECTS

(Adverse effects)

IN COMMON WITH ALL ACTIVE SUBSTANCES, THIS MEDICINE MAY CAUSE TROUBLESOME EFFECTS OF VARYING DEGREES IN **CERTAIN INDIVIDUALS:**

- a very few allergic skin reactions have been reported. 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 heat and humidity.

DATE OF REVIEW OF PACKAGE INSERT INFORMATION

October 1996.