

Spasfon[®]

phloroglucinol 80mg/triméthylphloroglucinol 80mg

IDENTIFICATION OF MEDICINE

Trade name of the medicinal product

SPASFON, coated tablet

Composition

Hydrated phloroglucinol 80,000 mg
corresponding amount of
anhydrous phloroglucinol 62,233 mg
Triméthylphloroglucinol 80,000 mg
per coated tablet

Excipients: monohydrated lactose, sucrose, polyvinyl acetate, wheatstarch, stearic acid, magnesium stearate, talc, gum Arabic, gelatine, titanium dioxide (E 171), erythrosine (E 127), carnauba wax.

Pharmaceutical form

Coated tablet

Pack of 30

Pharmaco-therapeutic classification

MUSCULOTROPIC ANTISPASMODIC

(A: digestive system and metabolism)

(G: genitourinary system)

Manufactured by

Laboratoires Macors

Rue des Cellottes

ZI Plaine des Isles

89000 Auxerre

France

For

Acino France SAS

5 rue Charles de Gaulle

94140 Alfortville

France

WHEN SHOULD THIS MEDICINE BE USED

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

This medicine **MUST NOT BE TAKEN**

- In case of allergy to any of its constituents
- In the presence of coeliac disease

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

Warnings

Because of the presence of sucrose, this medicine must not be used in patients with fructose intolerance, glucose - galactose malabsorption syndrome or sucrose-isomaltase insufficiency (rare metabolic diseases).

Because of the presence of lactose, this medicine must not be used in patients with galactosemia, glucose - galactose malabsorption syndrome or lactase deficiency (rare metabolic diseases).

Precautions

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

ALWAYS KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Drug interactions and other interactions

IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU SHOULD ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER 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.

List of excipients of which awareness is necessary to ensure risk-free use in certain patients

Wheat starch (may be harmful in the presence of coeliac disease), sucrose, lactose.

HOW TO USE THIS MEDICINE

Dosage

6 tablets a day

Method and route of administration

Oral route. Swallow the tablets.

UNDESIRABLE AND TROUBLESOME EFFECTS

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

- skin and subcutaneous and allergic reactions: rash, rarely urticaria, exceptional angioedema, hypotension, anaphylactic 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.

DATE OF REVIEW OF PACKAGE INSERT INFORMATION

October 2008