

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SYMPATHYL, film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Heavy magnesium oxide	124.35 mg
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Quantity corresponding to 75 mg of elemental magnesium, i.e.	6.2 mEq
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Hawthorn (*Crataegus monogyna* Jacq. and/or *C. laevigata* DC.)

(dry extract of flowering tops) 7	5.00 mg
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Extraction solvent: ethanol 60% v/v

Drug extract ratio: 2.8-3.8: 1

Eschscholtzia (*Eschscholtzia californica* Cham.)

(dry extract of flowering aerial parts)	20.00 mg
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Extraction solvent: ethanol 60% v/v

Drug extract ratio: 3.5: 1

For one film-coated tablet

Excipients with known effect: azorubine (E122).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SYMPATHYL, film-coated tablet is indicated to adults.

Traditionally used in:

the symptomatic treatment of neurotonic states in adults, minor sleep disorders, disorders due to cardiac erethism in adults with a healthy heart.

4.2. Posology and method of administration

For adults only.

The usual dose is 4 tablets per day, 2 in the morning and 2 in the evening, before meals.

Pediatric population

The safety and efficacy of SYMPATHYL, film-coated tablet in adolescents and children under 18 years of age have not been established.

Method of administration

Oral route.

The tablets should be taken before meals.

Duration of treatment

The usual duration of treatment is 30 days.

4.3. Contraindications

- ☐ hypersensitivity to the active substances or any of the excipients listed in section 6.1;
- ☐ severe renal impairment (creatinine clearance under 30ml/min/1.73 m²)

4.4. Special warnings and precautions for use

This drug contains an azo colouring agent (E122) and may cause allergic reactions.

This medicinal product should generally not be prescribed in combination with quinidine (see section 4.5).

4.5. Interactions with other medicinal products and other forms of interaction

Combination not recommended:

+ Quinidinics

Increased plasma concentrations of quinidine and risk of overdose (decreased renal excretion of quinidine because of urine alkalinisation).

4.6. Pregnancy and lactation

Pregnancy

Safety in pregnant women has not been established. In the absence of sufficient data, the use of this medicine is not recommended during pregnancy

Lactation

In the absence of data concerning extracts of eschscholtzia and hawthorn, and because magnesium can pass into human milk, the use of this medicinal product should be avoided during breast-feeding.

Fertility

No fertility data is available.

4.7. Effects on the ability to drive and use machines

The effects on the ability to drive and use machines have not been studied.

4.8. Undesirable effects

The undesirable effects mentioned below are listed by system organ class and frequency according to the following classification: very common ($\geq 1/10$), common ($\geq 1/100$, $<1/10$), uncommon ($\geq 1/1,000$, $<1/100$), rare ($\geq 1/10,000$, $<1/1,000$), very rare ($<1/10,000$), frequency not known (cannot

be estimated from the data available).

System Organ Class	Undesirable effects (MedDRA terminology)	Frequency
Immune system disorders	Hypersensitivity reactions including eyelid swelling, palpitations, pruritus, abdominal distension, abdominal pain upper, myalgia, pyrexia	not known
Gastrointestinal disorders	Diarrhea, abdominal pain	not known

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting systems. Overdose

In the event of massive ingestion, there is a risk of anuric syndrome.

Treatment: rehydration, forced diuresis. In the event of renal impairment, haemodialysis or peritoneal dialysis is necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: PHYTOTHERAPY AND MINERAL ELEMENTS INTENDED FOR SEDATION

On a physiological basis:

Magnesium is a cation principally intracellular. It reduces neuronal excitability and neuromuscular transmission, and is involved in numerous enzymatic reactions. Magnesium is a structural element and half of the amount in the body is in bone.

Clinically, magnesium blood levels:

- between 12 and 17 mg/l (1 to 1.4 mEq/l or 0.5 to 0.7 mmol/l) indicates moderate magnesium deficiency,
- less than 12 mg/l (1 mEq/l or 0.5 mmol/l), indicates severe magnesium deficiency.

Magnesium deficiency can be

- primary due to congenital anomaly of metabolism (chronic congenital hypomagnesemia),
- secondary, caused by
 - insufficient magnesium intake (severe malnutrition, alcoholism, exclusive parenteral nutrition);

- intestinal malabsorption (chronic diarrhea, digestive fistulas, hypoparathyroidism); increased renal loss (due to tubule disease, significant polyuria, abuse of diuretics, chronic pyelonephritis, primary hyperaldosteronism, treatment with cisplatin).

5.2. Pharmacokinetic properties

Intestinal absorption of magnesium salts is governed, among others, by a passive mechanism for which the solubility of the salt is determinant. Intestinal absorption of magnesium salts does not exceed 50%. Excretion is mainly in the urine.

5.3. Preclinical safety data

6. Preclinical data are incomplete. No genotoxicity, carcinogenicity or reproductive toxicity tests have been performed with the dried extracts of eschscholtzia, hawthorn or magnesium oxide contained in SYMPATHYL, film-coated tablets. **PHARMACEUTICAL PARTICULARS**

6.1. List of excipients

Microcrystalline cellulose, sodium starch glycolate (type A), micronised stearic acid, shellac, povidone, Acetylated monoglyceride, hypromellose, titanium dioxide, macrogol 6000, Indigo carmine lake (E132), azorubine (E122), yellow iron oxide.

6.2. Incompatibilities

Not Applicable

6.3. Shelf life

3 years

6.4. Special precautions for storage

Store at temperature below 25°C.

6.5. Nature and contents of container

Box of 40 film-coated tablets, in blisters (PVC/Aluminium).

6.6. Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE INNOTECH INTERNATIONAL

22 avenue Aristide Briand

94110 ARCUEIL

8. MARKETING AUTHORISATION NUMBER

348 621.0: 40 tablets in blisters pack (PVC/Aluminium).

348 622.7: 60 tablets in blisters pack (PVC/Aluminium).

358 885.0: 120 tablets in blisters pack (PVC/Aluminium).

559 945.0: 600 tablets in blisters pack (PVC/Aluminium).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

3 May 1993 / 3 May 2009

10. DATE OF REVISION OF THE TEXT

24 December 2019

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARING RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS FOR PRESCRIPTION AND SUPPLY

Not subject to medical prescription.