

PACKAGE LEAFLET: INFORMATION FOR THE USER

SYMPATHYL®

film-coated tablet

Eschscholtzia, Hawthorn, Heavy magnesium oxide

Please read this leaflet carefully before taking this medicinal product because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What is SYMPATHYL, film-coated tablet and what it is used for
2. What you need to know before you take SYMPATHYL, film-coated tablets
3. How to take SYMPATHYL, film-coated tablets
4. Possible side effects
5. How to store SYMPATHYL, film-coated tablets
6. Contents of the pack and other information

1. WHAT SYMPATHYL, film-coated tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class: PHYTOTHERAPY AND MINERAL ELEMENTS WITH A SEDATIVE EFFECT.

This medicine is a mild tranquilizer.

It is recommended for adults:

- to reduce nervousness or in the event of excessive perception of the heart beat (palpitations) after any cardiac disease has been excluded;
- in the event of mild sleep disorders.

You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SYMPATHYL, film-coated tablet

Never take SYMPATHYL, film-coated tablet:

- if you are allergic (hypersensitive) to the active substances or one of the other constituents of this medicine listed in section 6.
- if you suffer from severe renal insufficiency (failure of kidney functions). This medicine SHOULD USUALLY NOT BE TAKEN, except advised by your doctor.
- if you are taking quinidine treatment or quinidine-like drugs treatment.

IF YOU HAVE ANY DOUBT, PLEASE ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Warnings and precautions

Talk to your doctor or pharmacist before taking SYMPATHYL, film-coated tablet.

This medicine contains an azoic colorant (E122) which can cause an allergic reaction.

IF YOU HAVE ANY DOUBT, PLEASE ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Other medicines and SYMPATHYL, film-coated tablet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine.

Generally speaking, you must not take this medicine at the same time as certain medicines used for heart rhythm disorders (quinidine and quinidine-like drugs) unless your doctor allows it.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

It is preferable not to use this medicinal product during pregnancy.

If you discover that you are pregnant during the treatment, see your doctor because he alone can judge the need to continue.

Avoid using this medicinal product when breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

SYMPATHYL, film-coated tablet contains azorubine (E122)

This medicine contains azorubine (E122) that may cause allergic reactions.

3. HOW TO TAKE SYMPATHYL, film-coated tablet

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage

ADULTS ONLY

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

Method and route of administration

Oral use.

Swallow the tablets with a glass of water.

Frequency of administration

Morning and evening before meals.

Duration of treatment

The treatment must not be extended without medical advice.

If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicinal products, this medicine can cause side effects, although not everybody gets them.

- Rare digestive disorders (diarrhoea, abdominal pain).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Competent Authority for pharmacovigilance in your country.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SYMPATHYL, film-coated tablets

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer packaging. The expiry date refers to the last day of that month. This medicinal product must be stored at a temperature of less than 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SYMPATHYL, film-coated tablet contains

The active substances are:

Eschscholtzia (dry aqueous extract)	20.00mg
Hawthorn (dry hydroalcoholic extract of the flower head)	75.00mg
Heavy magnesium oxide	124.35 mg
quantity corresponding to 75mg of magnesium element, i.e	6.2mEq

For one film-coated tablet.

The other constituents are:

Microcrystalline cellulose, sodium carboxymethyl starch (type A), micronized stearic acid, gum lac, polyvidone, acetylated monoglyceride, hypromellose, titanium dioxide, macrogol 6000, indigo carmine lake, azorubine, yellow iron oxide.

What is SYMPATHYL, film-coated tablet and contents of the pack

This medicinal product is in the form of a film-coated tablet.

Box of 40 film-coated tablets.

Marketing Authorization Holder

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Manufacturer

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