

Symphocal® Syrup

Composition

Symphocal®

Honey-lemon-flavoured Syrup

Each 5 ml contains
Oxolamine Citrate
50 mg

Symphocal®

Raspberry-flavoured Syrup

Each 5 ml contains
Oxolamine Citrate
50 mg

For the list of inactive ingredients in the preparation, see section 6 – “Further information”.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the relief of dry cough.

Therapeutic group:

Cough suppressants.

2. BEFORE USING THE MEDICINE

Do not use this medicine

- If there is a known sensitivity to any of the ingredients of the preparation
- In infants below one year of age

Special warnings regarding use of the medicine

Consult a doctor before commencing treatment if you are suffering, or have suffered in the past, from:

- Diabetes - the preparation contains 1.925 gram sorbitol in each 5 ml. The recommended dosage for adults may exceed the allowed daily intake of sorbitol for diabetics (which is 25 grams per day).
- If you are suffering, or have suffered in the past, from impaired liver function.

Additional warnings

If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

If you are taking, or have recently taken, other medicines

including non-prescription medicines, herbal medicines and food supplements and vitamins, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking anticoagulants.

Pregnancy and breastfeeding

Inform the doctor if you are pregnant or breastfeeding.

Driving

Use of this medicine does not affect the ability to drive or to operate machinery.

Use in children

This medicine is not intended for use in infants below one year of age.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The usual dosage unless otherwise instructed by the doctor

Children 1-6 years of age: requires a doctor's prescription.

Children 6-12 years of age: 10 ml every 4 hours.

Adults and children over 12 years of age: 15-30 ml every 4 hours.

Wait 4 hours before taking an additional dose.

If there is no improvement in your condition within 7 days, refer to a doctor.

Use this medicine at specified time intervals, as determined by the attending doctor.

Do not exceed the recommended dose.

Even if there is an improvement in your health condition, do not discontinue treatment with the medicine without consulting the doctor.

Directions for use

Be sure to measure the dose with the provided measuring spoon.

The bottle is closed with a Kid Lock, which is a cap designed to prevent it from being opened by children. To open the bottle, press down and turn to the left while pressing. See diagram.



If you took an overdose, or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. Do not induce vomiting without explicit instruction from the doctor! Even if you feel well, immediate treatment is essential.

If you forgot to take this medicine at the specified time, take the dose as soon as you remember, but never take two doses together.

Do not take medicines in the dark! Check the label and the dose **each time** you take medicine. Wear glasses if you need them.

4. SIDE EFFECTS

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

- When using it, side effects such as gastric discomfort or heartburn may occur. These effects can be prevented by taking the medicine after meals.
- Slight numbness in the oral cavity which disappears within a short time.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor immediately.

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Keep this medicine in a dark place below 25°C.

The medicine can be used for up to 6 months after first opening the bottle, but no later than the expiry date.

Even when stored as per the recommended packaging/storage conditions, medicines may be kept for a limited period only. Please note the expiry date of the preparation! In any case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Symphocal® honey-lemon-flavoured Syrup

Sorbitol, povidone K-90, propylene glycol, citric acid, sodium cyclamate, saccharin, methylparaben, honey flavour, color E-150 (caramel powder), propylparaben, water.

Each 5 ml contains 1.14 mg sodium and 1.925 gram sorbitol.

The recommended dosage for adults may exceed the allowed daily intake of sorbitol for diabetics (which is 25 grams per day).

Each 5 ml contains 10 mg sodium cyclamate and 5 mg saccharin.

Symphocal® raspberry-flavoured Syrup

Sorbitol, propylene glycol, citric acid, raspberry flavour, alcohol, sodium cyclamate, saccharin, methylparaben, edicol supra red 4R ponceau, propylparaben, water.

Each 5 ml contains 1.14 mg sodium and 1.925 gram sorbitol.

The recommended dosage for adults may exceed the allowed daily intake of sorbitol for diabetics (which is 25 grams per day).

Each 5 ml contains 10 mg sodium cyclamate and 5 mg saccharin.

What the medicine looks like and what are the contents of the package:

Symphocal honey-lemon-flavoured syrup: a clear, light-brown syrup.

A plastic bottle containing 115 ml.

Symphocal raspberry-flavoured syrup: a clear, red syrup.

A plastic bottle containing 100 ml.

Manufacturer and license holder:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by the Ministry of Health on 20/3/2014.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:

Symphocal honey-lemon-flavoured syrup:

028.22.21621.00

Symphocal raspberry-flavoured syrup:

112.86.27640.00