

פורמט עלון זה נקבע ע"י משרד הבריאות ותוכנו נבדק ואושר". עלון מאושר : אוגוסט 2007
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SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Symphocal Honey and Lemon Flavour Syrup

Symphocal Raspberry Flavour Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Symphocal Honey and Lemon Flavour Syrup

Clear light brown color syrup.

Symphocal Raspberry Flavour Syrup.

Clear red color syrup.

Each teaspoonful (5 ml) contains Oxolamine citrate 50 mg

For excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup.

4. CLINICAL DATA

4.1 THERAPEUTIC INDICATIONS

Cough suppressant.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults and Children over 12 Years of Age

1-2 tablespoonfuls, every 4 hours.

Children

Important note: this product is not usually recommended for children under 2 years of age

1-2 Years of Age

1 teaspoonful, every 4 hours.

2-12 Years of Age

2 teaspoonfuls, every 4 hours.

4.3 CONTRAINDICATIONS

Known hypersensitivity to the components of the drug or chemically-related substances.

Not for use in infants under the age of one year.

4.4 SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Do not use for long-term treatment. If no significant results are obtained after a short period of treatment with Symphocal a physician should be consulted.

This preparation contains 1.925 g of sorbitol in each 5 ml. It has been reported that the maximum allowed daily intake of sorbitol for diabetics is 25 g. It should be noted that the amount of sorbitol included in the adult dosage of Symphocal syrup may extend beyond the allowed daily consumption of sorbitol for diabetics.

Keep the product out of reach of children.

4.5 INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION.

Patients under treatment with anticoagulants should consult their physician prior to taking Symphocal.

4.6 PREGNANCY AND LACTATION.

Although contraindications to the use of Symphocal have not been reported, pregnant women are advised to use the drug under the direct supervision of a physician.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The use of Symphocal does not interfere with the capacity to drive or to use machinery.

4.8 UNDESIRABLE EFFECTS

Symphocal may occasionally cause gastric discomfort or heartburn. These disturbances can be prevented by taking the drug after meals. Symphocal syrup may produce a mild anesthetic sensation of the oral cavity which rapidly subsides.

4.9 OVERDOSE

There have been no reports of overdosage with the use of Symphocal.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Oxolamine is a substance with anti-inflammatory effects, mainly on the respiratory tract, and specific antitussive and bronchospasmodic activity. The antitussive action of Symphocal is mainly due to its anti-inflammatory activity which causes a reduction in the irritation of the nervous receptors of the respiratory tract. Consequently, there is a progressive relief of cough as the inflammatory condition subsides.

5.2 PHARMACOKINETIC PROPERTIES

Orally-administered oxolamine is rapidly metabolized and completely eliminated through the urine and feces within 24 hours.

5.3 PRECLINICAL SAFETY DATA

Toxicological studies on different animal species have shown that oxolamine is well tolerated and does not produce teratogenic or mutagenic effects. LD₅₀ of the oral substance ranges between 650 and 2,500 mg/kg in the different animal species tested.

6. PHARMACEUTICAL INFORMATION

6.1 LIST OF EXCIPIENTS

Symphocal Honey and Lemon Flavour

Sorbitol, povidone, propylene glycol, citric acid, sodium cyclamate, saccharine, methylparaben, honey flavour, caramel powder, propylparaben, purified water.

Each 5 ml contains:

Sorbitol: 1.925 g

Sodium: 1.14 mg

Sodium cyclamate: 10 mg

Saccharin: 5 mg

Symphocal Raspberry Flavour

Sorbitol, propylene glycol, citric acid, raspberry flavour, alcohol, sodium cyclamate, saccharine, methylparaben, cochineal red, colour index Food Red 7, propylparaben, purified water.

Each 5 ml contains:

Sorbitol: 1.925 g

Sodium: 1.14 mg

Sodium cyclamate: 10 mg

Saccharin: 5 mg

6.2 INCOMPATIBILITIES

There have been no reports of drug incompatibilities except for that reported in section 4.5.

6.3 SPECIAL PRECAUTIONS FOR STORAGE

Store in a dark place below 25°C.

The product may be used up to 6 months following first opening of the bottle, but no later than the expiry date.

6.4 NATURE AND CONTENTS OF CONTAINER

Symphocal Honey and Lemon Flavour: Bottles of 115 ml.

Symphocal Raspberry Flavour: Bottles of 100 ml.

7. DRUG REGISTRATION NUMBERS:

Symphocal Honey and Lemon Flavour : 028 22 21621 00.

Symphocal Raspberry Flavour : 112 86 27640 00.

8. MANUFACTURER & LICENCE HOLDER

Teva Pharmaceutical Industries Ltd,
P.O.Box 3190, Petach Tikva.