SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SOLACY ADULT, capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

L-Cystine ..... 72.6 mg
Precipitated sulphur..... 22.0 mg
Coated vitamin A acetate*
quantity equivalent to retinol ..... 1650 IU
**Yeast (*Saccharomyces cerevisiae*)..... 77.4 mg

for one capsule

*Composition of coated vitamin A acetate: crystallized vitamin A acetate containing 500,000 IU/g, gelatin, sucrose, maize starch, antioxidant (BHT).

**Yeast (*Saccharomyces cerevisiae)*: produced by high fermentation of washed and dried *Saccharomyces cerevisiae*.

Excipients with a known effect: sucrose

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule.

4. CLINICAL DATA

4.1 Therapeutic indications

Symptomatic adjunctive treatment of rhinopharyngeal disorders in adults.

4.2 Dosage and method of administration

FOR ADULTS ONLY.

3 capsules per day, for 3 months.
Swallow the capsules with a glass of water, preferably during a meal.

4.3 Contraindications

Allergy to one of the ingredients.

4.4 Special warnings and precautions for use

This medicinal product contains vitamin A; consider the doses administered in case of concomitant intake of any other medicine containing vitamin A.

Due to the presence of sucrose, this medicine is contraindicated in patients with fructose intolerance (rare hereditary disease).

4.5 Interactions with other medicinal products and other forms of interaction

Data available to date do not suggest existence of clinically significant interactions.

4.6 Pregnancy and breast-feeding

- Pregnancy
Vitamin A is teratogenic in several animal species.

In human beings, malformations have been reported with high doses. However, to date, the lack of reliable epidemiological study and the small number of isolated reports prevent any definitive conclusion with respect to the risk of malformation.
Consequently, given the daily food intake, it is recommended not to exceed a daily dose of 5000 IU of vitamin A supplied by medicines.

- Breast-feeding
At high doses, there is a risk of overdose in neonates.
Consequently, given the daily food intake, it is recommended not to exceed a daily dose of 5000 IU of vitamin A supplied by medicines.

4.7 Effects on the ability to drive vehicles and use machines

No effect on the ability to drive vehicles and use machines was observed.

4.8 Adverse effects

Some cutaneous reactions have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Agence nationale de sécurité du medicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.ansm.sante.fr

4.9 Overdose

Following a massive intake, signs of hypervitaminosis A are possible.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Trophic for the respiratory mucosa.
(R. Respiratory system)
Combination of sulphur, vitamin A and yeast, intended to reduce inflammation of the rhinopharyngeal mucosa. The inclusion of vitamin A confers immunostimulant properties.

5.2 Pharmacokinetic properties

Not specified

5.3 Preclinical safety data

Not specified

6. PHARMACEUTICAL DATA

6.1 Excipients

Magnesium stearate
Composition of the capsule shell: gelatin, titanium dioxide (E171).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

15 capsules in PVC/PE/PVDC/aluminium blister; boxes of 45 or 90 capsules.

6.6 Special precautions for disposal and handling

No particular requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG
19, rue Poliveau
75005 PARIS
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

317 395-9: 45 capsules in blister (PVC/PE/PVDC/Aluminium)
355 722-3: 90 capsules in blister (PVC/PE/PVDC/Aluminium)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

7 March 1996

10. DATE OF TEXT UPDATE
13 January 2012.