SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

SOLACY ADULT, capsule

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 "List of excipients"

PHARMACEUTICAL FORM

Capsule.

CLINICAL PARTICULARS

Therapeutic indications

Symptomatic adjunctive treatment of rhinopharyngeal disorders in adults.

Posology and method of administration

Posology

FOR ADULTS ONLY.

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

Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section "List of excipients"

Due to the presence of vitamin A, SOLACY ADULTS, capsule should not be associated with:

- cyclines in case of intake of 10 000 UI/d or more of vitamin A
- retinoids

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).

Interactions with other medicinal products and other forms of interactions

Contraindicated associations:

Due to the presence of vitamin A

+ CYCLINES
In case of intake of 10 000 IU/d or more of vitamin A, there is a risk of intracranial hypertension.

+ RETINOIDS
Risk of suggestive symptoms of hypervitaminosis A.

Fertility, 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.

Effects on ability to drive and use machines

No effect on the ability to drive and use machines was observed with SOLACY ADULTS.

Undesirable effects

Some cutaneous reactions have been reported.

Reporting of suspected undesirable effects
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.signalement-sante.gouv.fr

Overdose

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

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Other cold preparations- ATC code: R05X

Pharmacodynamic effects
Combination of sulphur, vitamin A and yeast, intended to reduce inflammation of the rhinopharyngeal mucosa. The content of vitamin A confers immunostimulant properties.

Pharmacokinetic properties

No information is available.

Preclinical safety data

No information is available.

PHARMACEUTICAL PARTICULARS

List of excipients

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

Shelf life

2 years.**Special precautions for storage**

Store at a temperature not exceeding 30°C.

Nature and contents of external container

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

Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with current regulations. .

7. MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret – France

8. MARKETING AUTHORISATION NUMBER(S)
34009 317 395 9 3: 45 capsules in blister (PVC/PE/PVDC/Aluminium)
34009 355 722 3 3: 90 capsules in blister (PVC/PE/PVDC/Aluminium)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION
7 March 1996 / 07 mars 2011

10. DATE OF REVISION OF THE TEXT
30 January 2019

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription