

## SUMMARY OF PRODUCT CHARACTERISTICS

### NAME OF THE MEDICINAL PRODUCT

**SOLACY ADULT, hard capsule**

### QUALITATIVE AND QUANTITATIVE COMPOSITION

L-Cystine .....	72.60 mg
Precipitated sulphur .....	22.00 mg
Coated vitamin A acetate* quantity equivalent to retinol.....	1650 IU
**Yeast <i>Saccharomyces cerevisiae</i> .....	77.40 mg

for one hard capsule

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

\*\*Yeast *Saccharomyces cerevisiae*: formed by a continuous 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

Hard 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.

##### Method of administration

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 ADULT, capsule should not be associated with:

- cyclins in case of intake of 10 000 UI/d or more of vitamin A
- retinoids (see section Interactions with other medicinal products and other forms of interactions)

#### Special warnings and precautions for use

Avoid prolonging the treatment in case of digestive intolerance.

This medicinal product contains vitamin A; (retinol), consider the doses administered in case of concomitant intake of any other medicine containing vitamin A. Each capsule contains 1650 IU of vitamin A (retinol), it is imperative to respect the recommended dosages.

This medicine contains sucrose. Patients with fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency (rare hereditary diseases) should not take this medicine.

## **Interactions with other medicinal products and other forms of interactions**

### **Contraindicated associations:**

#### **+ CYCLINS**

In case of intake of 10 000 IU/d or more of vitamin A (which represents more than 2 times the recommended daily dose of SOLACY ADULT):risk of intracranial hypertension.

#### **+ RETINOIDS**

Risk of suggestive symptoms of hypervitaminosis A.

## **Fertility, pregnancy and lactation**

### **Pregnancy**

Vitamin A is teratogenic in several animal species.

In human beings, malformations have been reported with high doses. However, so far , the lack of reliable epidemiological study and the small number of isolated reports prevent any definitive conclusion regarding the malformation risk.

Consequently, given the daily food intake, it is recommended not to exceed a daily dose of 5000 IU of vitamin A supplied by medicines.

### **Lactation**

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**

SOLACY ADULT. has no influence on the ability to drive and use machines.

## **Undesirable effects**

Some cutaneous reactions have been reported.

Possibility of digestive disorders.

### **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 médicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr)

## **Overdose**

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

## **PHARMACOLOGICAL PROPERTIES**

### **Pharmacodynamic properties**

**Pharmacotherapeutic class : 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.

## **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 container**

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

### **Special precautions for disposal and other handling**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## **MARKETING AUTHORISATION HOLDER**

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

## **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)

## **DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION**

7 March 1996 / 07 mars 2011

## **DATE OF REVISION OF THE TEXT**

08 September 2020

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## **PRESCRIBING AND DISPENSING CONDITIONS**

Medicinal product is not subject to medical prescription