SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

SOLACY PEDIATRIC, tablet for oral suspension.

QUALITATIVE AND QUANTITATIVE COMPOSITION

L-cystine ..... 36.30 mg
Precipitated sulphur..... 11.00 mg
Coated vitamin A acetate *
quantity equivalent to retinol.....1000 IU
Saccharomyces cerevisiae yeast** ..... 38.70 mg

per a tablet.

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

** *Saccharomyces cerevisiae* yeast: produced by continuous fermentation of washed and dried Saccharomyces cerevisiae.

Excipient with known effect: sucrose

For a full list of excipients, see section “List of excipients”.

PHARMACEUTICAL FORM

Tablet for oral suspension

CLINICAL PARTICULARS

Therapeutic indications

Symptomatic adjunctive treatment of rhinopharyngeal disorders in an infant over 6 months old and in a child. .

Posology and method of administration

Posology

Pediatric population

- ONLY FOR INFANTS OF OVER 6 MONTHS OLD AND CHILDREN. From 6 months to 30 months: 1 tablet daily for 3 months
- from 30 months to 5 years: 2 tablets daily for 3 months
- from 5 years: 3 tablets daily for 3 months.

Method of administration

It is IMPERATIVE to dilute the tablet in a little water or other cold liquid before taking this medicine since the intake of fully undiluted tablet by children aged under 6 years old may induce false route. Preferably to be taken 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 PEDIATRIC tablet for oral suspension. should not be associated with:

- Cyclins in case of intake of 10,000 IU / day 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 prolonged treatment in the event of digestive intolerance.

This medicinal product contains vitamin A (retinol); consider the doses administered in case of simultaneous intake of any other medicine containing vitamin A. Each tablet contains 1000 IU of vitamin A (retinol), it must be complied with the recommended dosages..

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

Interactions with other medicinal products and other forms of interactions

Contraindicated associations

+ CYCLINS

In case of intake of 10,000 IU / day and more of vitamin A (which is more than 3 times the dose provided by SOLACY PEDIATRIC in children from 5 years old): risk of intracranial hypertension

+ RETINOIDS

Risk of symptoms suggestive of hypervitaminosis A.

Fertility, pregnancy and lactation

This product is intended for children. However, indications in the event of pregnancy and breastfeeding are given for information.

Pregnancy

Vitamin A is teratogenic in several animal species.

In humans, 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, adults should not 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.

In consequence, given the daily food intake, adults should not exceed a daily dose of 5000 IU of vitamin A supplied by medicines.

Undesirable effects

Potential digestive disorders such as stomach ache.
Some skin 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.signalement-sante.gouv..fr

Overdose

In case of 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 attenuate the inflammation of the rhinopharyngeal mucosa. The presence of vitamin A confers immunostimulating properties.

PHARMACEUTICAL PARTICULARS

List of excipients

Microcrystalline cellulose, magnesium stearate, anhydrous citric acid, sodium cyclamate, strawberry flavour***

*** Composition of strawberry flavour: maltodextrin, gum arabic, dextrose, gamma-undecalactone, butyric acid, cinnamyl butyl-isobutyrate butyryl lactate, diacetyl, di-n-propylketone, ethyl isovalerianate, heliotropyl acetate, methyl octine carbonate, methyl salicylate, ethyl vanillin, vanillin, maltol, ethylmaltol, heliotropin, betanaphthylethyl ether, benzaldehyde.

Shelf life

2 years.

Special precautions for storage

To be stored at a temperature not exceeding 30°C.

Nature and contents of container

60 tablets in blisters (PVC/PE/PVDC90/aluminium)

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 NUMBERS

34009 333 715 4 8: 60 tablets in blisters (PVC/PE/PVDC/aluminium)

DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION

08 September 1988/ 08 June 2009

DATE OF REVISION OF THE TEXT

08 September 2020

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription