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 243.00 mg 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 high 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 children older than 6 months.
Solacy pediatric is indicated in infants aged more than 6 months and children

Posology and method of administration

Posology

Pediatric population

ONLY FOR infants of over 6 months old and children.

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 less than 6 years may induce false route. Preferably to be taken during a meal.

- from 6 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.

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 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 should be complied with the recommended dosages in order not to observe compulsory the recommended daily nutritional intakes of vitamin A

This medicine contains sucrose. Its use is not advised in patients presenting fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase deficiency.

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 pediatric Solacy in children from 5 years), there is a risk of intracranial hypertension

Retinoids
Due to the presence of vitamin A, concomitant administration of pediatric Solacy and retinoid, there is a risk of symptoms suggestive of hypervitaminosis.

Fertility, pregnancy and breastfeeding
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.

Breastfeeding
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.

Effects on ability to drive and use machines:
Effects of Solacy pediatric on ability to drive and use machines have not been studied.

Undesirable effects:
Potential digestive disorders such as stomach ache.

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:
In case of massive intake, signs of hypervitaminosis A are possible.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties
Pharmacotherapeutic group: Other cold preparations- ATC code: R05X
(R: respiratory system)

Combination of sulphur, vitamin A and yeast, intended to attenuate the inflammation of the rhinopharyngeal mucosa.

Pharmacokinetic properties:
No information is available.

Preclinical safety data:
No information is available.

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 product or waste material should be disposed of in accordance with local regulations.

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/PVDC90/aluminium)

DATE OF FIRST AUTHORISATION/ RENEWAL OF AUTHORISATION
08 September 1988/ 08 June 2009

DATE OF REVISION OF THE TEXT
12 October 2018

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription