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 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 MANDATORY to dilute the tablet in a little water or other cold liquid before taking this medicine since the intake of 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 10000 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

Special warnings

Avoid prolonged treatment in the event of digestive intolerance.

The risk of hypervitaminosis A and vitamin A toxicity may increase with concomitant administration of other vitamin A-containing drugs or food supplements containing vitamin A.

To avoid the risk of overdose:
• check the absence of vitamin A in the composition of other medicines, including those obtained without prescription
• each tablet containing 1000 IU of vitamin A (retinol), follow the recommended maximum doses (see section "Posology and Method of administration")

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

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, this is essentially "sodium-free".

Interactions with other medicinal products and other forms of interactions

Contraindicated associations

+ CYCLINS

In case of intake of 10000 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, the actions to take 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

Adverse events following administration of SOLACY PEDIATRIC are presented below:

Skin and subcutaneous tissue conditions	
Unknown frequency	Rash, Pruritus Urticaria, Dry skin Erythema
Gastrointestinal conditions	
Unknown frequency	Abdominal pain Nausea Vomiting Diarrhea

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: https://signalement.social-sante.gouv.fr/

Overdose

An overdose of vitamin A may occur if the maximum recommended doses in section 4.2 are not met and/or if it is combined with other vitamin A-containing medicinal products.

Reminder of clinical signs of vitamin A overdose.

Acute vitamin A intoxication (greater than 300000 IU):
Digestive disorders (abdominal pain, nausea, vomiting), headache, intracranial hypertension, papillary oedema, irritability, delayed generalized desquamation.

Chronic intoxication:
The maximum recommended daily intake is 2700 IU for infants from 12 to 36 months, 3600 IU for children from 4 to 6 years, 5000 IU for children from 7 to 10 years and 6600 IU for children from 11 to 14 years.
Early symptoms of chronic intoxication are: alopecia, dry and scaly skin, dry eyes, chapped lips.
Later, the following symptoms can develop: severe headache, idiopathic intracranial hypertension (possible occurrence of fontanel bulge in infants), generalized weakness.
In children, cortical bone hyperostoses and arthralgia may occur. Chronic intoxication can also lead to pruritus, anorexia, growth retardation.
Hepatosplenomegaly can sometimes be observed.

Action to be taken in case of acute or chronic overdose:
The treatment of an overdose in SOLACY PEDIATRIC consists in stopping the administration of SOLACY PEDIATRIC and taking additional measures according to the clinical condition of the patient.
Symptoms of chronic intoxication usually disappear within 1 to 4 weeks.

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/PVDC/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 – 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

03 August 2023

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription