

Package leaflet: information for the user

SOLACY PEDIATRIC, tablet for oral suspension

L-cystine, coated vitamin A acetate, precipitated sulphur, saccharomyces cerevisiae yeast

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine following scrupulously the information provided in this leaflet or by your doctor or by your pharmacist

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist for any advice or information.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

You must talk to your doctor if you do not feel better or if you feel worse

What does this leaflet contain?

1. WHAT SOLACY PEDIATRIC, tablet for oral suspension IS AND WHAT IT IS USED FOR?
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLACY PEDIATRIC, tablet for oral suspension?
3. HOW TO TAKE SOLACY PEDIATRIC, tablet for oral suspension?
4. POSSIBLE SIDE EFFECTS
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1. WHAT SOLACY PEDIATRIC, tablet for oral suspension IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group: Other cold medications, ATC code: R05X (R: respiratory system)

Symptomatic adjunctive treatment of rhinopharyngeal diseases in infant over 6 months and children.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOLACY PEDIATRIC, tablet for oral suspension?

Never use SOLACY PEDIATRIC, tablet for oral suspension:

- if you are allergic (hypersensitive) to the actives substances or or one of the other ingredients of this medicine listed in section 6
- If you take a dose of 10 000 IU/day or more of vitamin A provided by Solacy, associated with an antibiotic of the class of cyclines
- If you take a medicine containing retinoids (derivatives of vitamin A)

Warnings and precautions

Talk to your doctor or pharmacist before taking SOLACY PEDIATRIC, tablet for oral suspension.

Avoid taking prolonged treatment in case of gastrointestinal intolerance.

This product contains vitamin A (retinol). Take into account the administered doses in case of concomitant intake of another product containing this vitamin. Each tablet contains 1000 IU of vitamin A (retinol), the recommended dosages should always be observed.

Other medicines and SOLACY PEDIATRIC, tablet for oral suspension:

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

You should not take Solacy pediatric if you take a medicine containing retinoids (derivatives of vitamin A)

You should not take an antibiotic of the class of cyclines associated with Solacy pediatric at a dosage supplying 10 000 IU/day or more of vitamin A. This would be more than 3 times the normal dosage of Solacy pediatric in children starting from 5 years old.

List of necessary information before taking the medicine:

If your doctor has informed you of any sugar intolerance, contact him/her before taking this medicine.

Use precautions and special warnings:

Use of this medicine is disadvised in patients presenting fructose intolerance, glucose-galactose malabsorption syndrome or sucrose-isomaltase deficiency (rare metabolic diseases).

Pregnancy and Breast-feeding

Although the use of this medicine is restricted to children, the attitude to be adopted during pregnancy and breast-feeding is indicated for information.

In pregnant adult women or breast-feeding women, given the daily dietary intake, it is recommended not to exceed a daily dose of 5000 IU of vitamin A taken in medicines.

Accordingly, do not exceed the dosage recommended by your doctor.

Solacy pediatric, tablet for oral suspension contains sucrose, a well-known excipient

3. HOW TO TAKE SOLACY PEDIATRIC, tablet for oral suspension?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- 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

Preferably to be taken during the meal

RESTRICTED to infants over 6 months and children

Treatment duration: in cure of 3 months

It is NECESSARY TO DILUTE THE TABLET in a little water or other cold liquid before taking this medicine since the intake of fully undiluted tablet by infants aged less than 6 years may induce aspiration (risk of aspiration and choking).

If you have taken more SOLACY PEDIATRIC, tablet for oral suspension than you should have:

In case of erroneous intake of an excessive dose, manifestations of vitamin A overdose may occur. Consult your doctor or pharmacist immediately.

If you forget to take SOLACY PEDIATRIC, tablet for oral suspension

Do not take a double dose to make up for a forgotten dose.

If you stop taking SOLACY PEDIATRIC, tablet for oral suspension

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Potential gastrointestinal disorders (stomach ache).

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Web site: www.signalement-sante.gouv.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOLACY PEDIATRIC, tablet for oral suspension?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the cardboard box. The expiry date refers to the last day of that month.

Store at a temperature not exceeding 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines which you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SOLACY PEDIATRIC, tablet for oral suspension contains?

The active substances are:

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 one tablet of 243 mg.

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

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

The other ingredients are: Microcrystalline cellulose, magnesium stearate, anhydrous citric acid, sodium cyclamate, strawberry flavor***.

***Composition of the 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, ethyl maltol, heliotropin, betanaphthylether, benzaldehyde

What SOLACY PEDIATRIC, tablet for oral suspension looks like and contents of the pack?

60 tablets for oral suspension in cardboard box.

Marketing Authorisation Holder:

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

Manufacturer:

Laboratoires GRIMBERG SA - ZA des Boutries - Rue Vermont - 78704 Conflans Sainte Honorine Cedex- France

This leaflet was last revised in October 2018.

Detailed information on this medicinal product is available on ANSM website (France)