

## Package leaflet: information for the patient

### SOLACY PEDIATRIC, tablet for oral suspension

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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 is in this leaflet?**

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?
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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**

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

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

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

##### **Do not take SOLACY PEDIATRIC, tablet for oral suspension:**

- if you are allergic (hypersensitive) to the active substances 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 PEDIATRIC, associated with an antibiotic of the cyclins class due to the risk of intracranial hypertension.
- If you take a medicine containing retinoids (derivatives of vitamin A) due to the risk of symptoms suggestive of hypervitaminosis A.

##### **Warnings and precautions**

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

This medicine contains vitamin A; other medicines contain it. Do not combine them in order not to exceed the maximum recommended dose (see the section 3 HOW TO TAKE SOLACY PEDIATRIC, capsule).

Avoid taking prolonged treatment in case of gastrointestinal intolerance.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

SOLACY PEDIATRIC, tablet for oral suspension contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially "sodium-free".

**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) or any other medicines or food supplements containing vitamin A.

You should not take an antibiotic of the class of cyclins 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.

**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.**

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

RESERVED FOR INFANTS OVER 6 MONTHS AND CHILDREN.

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

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 take more SOLACY PEDIATRIC, tablet for oral suspension than you should :**

In case of erroneous intake of an excessive dose, manifestations of vitamin A overdose may occur. Stop taking treatment and consult your doctor or pharmacist immediately.

The most common symptoms of excessive vitamin A absorption (sudden or chronic) are:

**For information purpose only:**

- Clinical signs of sudden overdose in vitamin A (greater than 300 000 UI per day) include:
  - o gastrointestinal disorders (abdominal pain, nausea, vomiting),
  - o nervous system disorders (headache, drowsiness, swelling of the optic nerve; ....), increased blood pressure in your head,
  - o irritability,
  - o skin disorders (delayed peeling of the skin).
- Signs of long-term overdose in vitamin A depend on the age of your child and include:
  - o headaches due to increased pressure in your head, fontanel bulge
  - o bone disorders (sensitive or painful swelling in the extremities of your limbs).
  - o skin disorders (dry and rough skin, itching)
  - o loss of appetite

- o abnormal development (stunting)
- o fractures, especially in postmenopausal women
- o increased liver and spleen volume

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

Do not take a double dose to make up for the dose you forgot. 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.

**Undetermined frequency of adverse reactions:** frequency cannot be estimated from available data

- Digestive disorders such as abdominal pain, nausea, vomiting and diarrhea,
- Rashes, itching, hives, dry skin, redness of the skin.

**Reporting of side effects:**

If you get any side effect, talk to your doctor or your pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via your national reporting system.

By reporting side effects, you can help provide more information on the safety of this medicine.

**4. 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 outer carton after EXP. 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.

**5. 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 tablet	

\*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, betanaphtylethylether, benzaldehyde

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

This medicine is in the form of a tablet for oral suspension. Box of 60.

**Marketing Authorisation Holder :**

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

**Manufacturer :**

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