PACKAGE LEAFLET

SOLACY® PEDIATRIC
tablet for oral suspension

Read all of this leaflet carefully before you start taking this medicine.
Keep this leaflet, you may need to read it again.
If you have any further questions, if you have any doubt, ask your doctor or pharmacist.
This medicine has been prescribed for you only. Never pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

QUALITATIVE AND QUANTITATIVE COMPOSITION

For a tablet of 243 mg :

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

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

Composition of coated vitamin A acetate at 500 000 UI/g, gelatin, sucrose, maize starch, antioxidant (BHT), - 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, betanatphtylethylether, benzaldehyde

For one tablet

PHARMACEUTICAL FORM: Tablet for oral suspension

PHARMACOTHERAPEUTIC CLASS
R05X: other cold preparations.
(R: respiratory system)

NAME AND ADDRESS OF THE OPERATING COMPANY: Laboratoires GRIMBERG - 19, rue Poliveau - 75005 Paris – France

NAME AND ADDRESS OF THE MANUFACTURER: Laboratoires GRIMBERG - ZA des Boutries - 5, rue Vermont - 78700 Conflans Sainte Honorine – France

WHEN IS THIS MEDICINE USED?

Symptomatic adjunctive treatment of rhinopharyngeal diseases in children older than 6 months.

BEWARE !

WHEN IS THIS MEDICINE NOT USED?

IF IN DOUBT, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

SPECIAL WARNINGS

Avoid prolonged treatment in case of gastrointestinal intolerance.

This product contains vitamin A (retinol). Take the doses administered into account in case of concomitant intake of another product containing this vitamin. Each tablet contains 1000 IU of vitamin A (retinol), it should be complied with the recommended dosages in order not to exceed the recommended daily nutritional intakes of vitamin A shown below:

- infants < 1 years = 1250 - 1330 IU
- children aged 1 to 3 years = 1330 IU
- children aged 4 to 12 years = 2000 - 2700 IU
- adolescents = 2700 - 3300 IU

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Due to the presence of sucrose, this medicine must not be used in case of fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase deficiency (rare metabolic diseases).

PRECAUTIONS FOR USE

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

IN ORDER TO PREVENT POTENTIAL INTERACTIONS BETWEEN SEVERAL MEDICINES, ALWAYS TELL YOUR DOCTOR OR PHARMACIST ABOUT ANY OTHER ONGOING TREATMENT and, in particular, report every intake of any medicines containing vitamin A.

PREGNANCY – BREAST FEEDING

Although the use of this medicine is restricted to children, the attitude to be adopted during pregnancy and lactation 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.

Do not exceed the dosage recommended by your doctor accordingly.

LIST OF EXCIPIENTS OF WHICHKNOWLEDGE IS NECESSARY FOR RISK-FREE USE BY CERTAIN PATIENTS: Sucrose.

HOW TO USE THIS MEDICINE?

DOSAGE

RESTRICTED to infants older than 6 months and children.

- 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.

METHOD AND ROUTE OF ADMINISTRATION
Oral route.

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).

FREQUENCY AND TIME OF MEDICINE ADMINISTRATION

Preferably to be taken during a meal.

TREATMENT DURATION Therapy duration is of 3 months.

WHAT TO DO IF YOU HAVE TAKEN AN OVERDOSE
In case of erroneous intake of an excessive dose, manifestations of vitamin A overdose may occur. Consult your doctor.

UNWANTED AND UNPLEASANT SIDE EFFECTS
Potential gastrointestinal disorders (stomach ache).

Statement of the side effects:
If you feel any adverse effect, tell it to your doctor or your pharmacist or your nurse. This also applies to any adverse effect which would not be mentioned in this leaflet. You can also declare adverse effects directly via the national system of statement: the National Agency for safety of medicines and health products (Ansm) and the Regional Centers of Pharmacovigilance. The web site: www.ansm.sante.fr.By reporting the adverse events, you contribute to supply more information on the medicine safety.

STORAGE
DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING

SPECIAL PRECAUTIONS FOR STORAGE:
Store at a temperature not exceeding 30°C.

DATE OF LEAFLET REVISION: 8th June 2005