

**USER INFORMATION PAMPHLET**  
**SENIORAL jarabe niños**  
Clocinizine dihydrochloride/phenylpropanolamine hydrochloride

**Read the whole of this prospectus in detail, because it contains information that will be important to you.**

This medication can be obtained without a prescription for the treatment of minor afflictions without the intervention of a doctor. However, you must use Senioral jarabe niños with care to obtain the best results.

-Keep this prospectus; you may need to read it again.

-If you have any doubts, consult your doctor or pharmacists.

This medicine has been prescribed to you and must not be given to others. It may harm them, even when their symptoms are the same as yours.

**In this prospectus:**

1. What are Senioral jarabe niños and what are they used for?
2. Before using Senioral jarabe niños
3. How to use Senioral jarabe niños
4. Possible adverse effects
5. Storage of Senioral jarabe niños

## **1.WHAT IS SENIORAL jarabe niños AND WHAT IS IT USED FOR?**

SENIORAL syrup for adults has two principal ingredients: clocinizine and phenylpropanolamine. Clocinizine belongs to the antihistamine group, drugs used for the alleviation of allergic reactions.

Phenylpropanolamine belongs to the adrenergic agonist group, which are used for the alleviation of nasal congestion.

SENIORAL syrup for adults is used solely for the temporary alleviation of nasal congestion in colds, rhinitis, and nasal congestion associated with sinusitis.

## **2. BEFORE TAKING SENIORAL jarabe niños**

**Do not take SENIORAL jarabe niños**

-If you are allergic (hypersensitive) to phenylpropanolamine, clocinizine or any of the other components of SENIORAL jarabe niños.

-If you have high blood pressure (arterial hypertension), if you have any thyroid illness (hyperthyroidism) or suffer heart problems (serious coronary illness or angina pectoris).

-If you are taking any medicine for depression or for Parkinson's disease, which inhibits the mono-amino-oxide (MAO) (see below: Use of other medicines).

-With children under 2.

**Be especially careful with SENIORAL jarabe niños**

-Do not exceed the maximum recommended dose (see **3.How to take SENIORAL jarabe niños**), as serious side effects can occur (see **If you take more SENIORAL jarabe niños than you should**).

-If you suffer from diabetes mellitus, have high ocular pressure (glaucoma) or present alterations of the prostate (prostatic hypertrophy) or urinary retention, as these conditions can worsen.

### **Use of other medicines**

Inform your doctor or pharmacist if you are taking or have recently taken other medicines, including those without prescription.

-If you use drugs that inhibit the mono-amino-oxide (MAO) enzyme, which are used for depression (tranylcypromine, moclobemide) or for Parkinson's disease (selegiline), serious side effects can occur which manifest themselves as strong headaches, sharp rises in temperature. If you have taken any of these medicines, wait **a minimum of 15 days before taking SENIORAL jarabe niños**. If you are not sure if your medication includes an MAO drug, consult your doctor before taking SENIORAL jarabe niños.

-If you are being treated with other medication, consult your doctor or pharmacist before taking SENIORAL jarabe niños.

### **Pregnancy and breast feeding**

Consult your doctor or pharmacist before taking any medicine.

Mothers who are breast feeding must not use this medicine, as it can pass through the milk to the child.

### **Driving and the use of machines**

Do not drive or use machines because SENIORAL can diminish your capacity to concentrate and reflexes.

### **Use in sportspeople**

We inform sportspeople that this medicine contains an ingredient that can produce a positive result in analytic doping tests.

### **Important information about some of the components of SENIORAL jarabe niños.**

This medicine contains 0.87% of ethanol (alcohol) by volume, which corresponds to a quantity of 103mg per dose, which is equivalent to 2 ml of beer or 0.86 ml of wine.

This medicine is prejudicial to those suffering from alcoholism.

The alcohol content must be considered in the case of pregnant women, or those breast feeding, children or high risk groups, such as those with liver diseases or epilepsy.

It can produce allergic reactions (possibly delayed) as it contains methyl parahydroxybenzoate (E-218).

This medicine contains sucrose. If your doctor has indicated that you suffer from intolerance to certain sugars, consult with him/her before taking this medication. Patients with diabetes mellitus need to bear in mind that this medicine contains 12.3 g of sucrose per dose (15ml).

### **3. HOW TO TAKE SENIORAL jarabe niños**

Follow the instructions given by your doctor exactly. Consult your doctor or pharmacist if you have doubts.

The standard dose is:

Children between 2 and 5: The maximum daily dose is 7.5ml three times a day, to be taken before meals with a minimum gap of 6 hours between doses.

Children between 5 and 12: The maximum daily dose is 15ml three times a day, to be taken before meals and with a minimum gap of 6 hours between doses.

If symptoms do not improve after 5 days or are accompanied by a high temperature, you must consult your doctor before continuing the treatment.

SENIORAL syrup for children is administered orally using the dosage glass.

The syrup must be taken before meals. A minimum gap of 6 hours must be left between doses. Remember to take your medicine.

#### **Use in children**

Do not use with those under 2.

#### **If you take more SENIORAL jarabe niños than you should**

If you have taken a higher dose than recommended you may suffer cardiac and neurologic alterations. In this case a gastric wash is needed and the symptoms will need to be treated. Consult your doctor or pharmacist.

If higher than recommended doses are taken these can cause nervousness, vertigo, palpitations, trembling, agitation and, very rarely hallucinations, convulsions and cerebral haemorrhages. If you have any of these symptoms, interrupt the use of this medicine immediately and consult your doctor.

In the case of excessive or accidental ingestion of SENIORAL jarabe niños, immediately go to your doctor or the Emergency Department at your nearest hospital, or consult the Toxicology Information Service (telephone: 915620420), indicating the medicine and the amount ingested. If possible, take this information pamphlet with you.

#### **If you forgot to take SENIORAL jarabe niños**

Do not take a double dose to compensate the forgotten ones. Take your dose as soon as possible. If it is less than 6 hours till when you should take the next dose, wait until this time to take your spoonful of syrup.

#### **If you interrupt your treatment with SENIORAL jarabe niños**

Your doctor will indicate the length of your treatment with SENIORAL jarabe niños. If you stop before the date indicated by your doctor, the symptoms of your illness may return.

If you have any doubts about the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

As with all medicines, SENIORAL jarabe niños can produce side effects, though not everyone suffers them.

Cardiovascular effects: Alterations of pulse (palpitations, tachycardia), increased blood pressure (hypertension), which on occasion can be serious (hypertensive crisis).

Effects on the nervous system: Intranquility, dizziness, lack of sleepiness, headaches, strange behaviour. Occasionally sedation or drowsiness can be produced.

Other side effects can be gastrointestinal discomfort (nausea and vomiting), constipation, confusion, euphoria, visual alterations, dry mouth and difficulty urinating.

If you consider that any of the side effects you suffer is serious or if you appreciate any side effect not mentioned in this pamphlet, inform your doctor or pharmacist.

#### **5. CONSERVATION OF SENIORAL jarabe niños**

Keep out of reach and sight of children.

Do not use SENIORAL jarabe niños after the expiry date which appears on the container. The expiry date is the last day of the month indicated.

Keep in the original container.

Medicines must not be disposed of in the drains or thrown away. Leave unwanted medicines and containers at the SIGRE point in a chemist. Ask your pharmacist how to dispose of any containers or unneeded medicines. This way you will help look after the environment.

#### **6. ADDITIONAL INFORMATION**

##### **Composition of SENIORAL jarabe niños**

-The principal components are: clocinizine dihydrochloride and phenylpropanolamine hydrochloride. Each 100ml of syrup contains 15mg of clocinizine dihydrochloride and 130mg of phenylpropanolamine hydrochloride. Each 15ml (a dose) of syrup contains: clocinizine dihydrochloride, 2.25mg and phenylpropanolamine hydrochloride, 19.5mg.

-The other components are: sucrose, ethanol, methyl parahydroxybenzoate (E-218), extract of cassis 30 GS 750, concentrated hydrochloric acid and purified water.

##### **Product appearance and container contents**

SENIORAL jarabe niños is a reddish syrup, which is presented in cases containing 150ml jars and a small dosage glass, with various measures marked.

##### **Holder of the authorisation for the commercialisation and fabrication of the product.**

LABORATORIOS ERN, S.A.  
Pedro IV, 499 - 08020 Barcelona, España

**Responsible for fabrication.**

LABORATORIOS ERN, S.A.

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**This pamphlet was approved in February 2001.**

Detailed and updated information about this product is available on the webpage of the Spanish Agency for Medicines and Health Products (AEMPS)

<http://www.aemps.gob.es/>