

PACKAGE LEAFLET: INFORMATION FOR THE USER

Neosayomol 20 mg/g cream
Diphenhydramine hydrochloride

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days of treatment.

What is in this leaflet:

1. What Neosayomol is and what it is used for.
2. What you need to know before you take Neosayomol.
3. How to use Neosayomol.
4. Possible side effects.
5. How to store Neosayomol.
6. Contents of the pack and other information

1. What Neosayomol is and what it is used for

Neosayomol is a cream composed of an antihistamine, diphenhydramine, that due to how it acts is effective in alleviating itchiness related with allergies.

This medication is indicated for adults and children over 6 years of age for local relief of symptoms of itchiness or burning sensations on the skin of allergic origin, produced by insect bites or stinging nettles.

2. What you need to know before you take Neosayomol

Do not use Neosayomol

- If you are allergic (hypersensitive) to diphenhydramine or any of the other ingredients of this medication.
- If you are using another medication that contains diphenhydramine or another allergy medication (antihistamines).
- On open wounds or infected skin.
- On children under 2 years of age.

Warnings and precautions

- It should not be applied on areas of open, erupted, bleeding or blistered skin, or large areas of skin.
- Avoid contact with eyes or other mucus membranes. Stop using the medication if a burning sensation or a skin rash are produced or if symptoms persist. If necessary, remove by washing with soap and water.
- To avoid possible photosensitivity reactions, you should protect the treated area from sun exposure.

Children

Its use in children under 6 years of age should be evaluated, as although the absorption is low, it can produce dryness of the skin and mouth, dilation of pupils, urine retention, increased heart beat, shaking, speech disorders, psychomotor hyperactivity and tiredness.

Aged over 65 years.

Its use in people over 65 years should be evaluated as they are more sensitive to the adverse effects of this medication.

Use of neosayomol with other medications

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

Do not use with other medications on the same area of skin, or with those that are known to produce allergic reactions on the skin (photosensitivity and phototoxicity reactions), without consulting a doctor.

Although high levels of absorption are not expected, part of this medication can pass into the blood stream, and therefore, the simultaneous use of Neosayomol with ototoxic medications (such as certain antibiotics) may mask the feeling of vertigo or dizziness.

Alcoholic beverages should not be consumed during treatment as simultaneous use may increase the sedative effect.

The concomitant use of Neosayomol with anticholinergic medications (such as anti-Parkinsonian agents, certain antidepressants, neuroleptics and belladonna) and with a medication called metoprolol (to decrease blood pressure and for heart disease) it could increase the adverse effects.

The use of Neosayomol with sedative medications (opioid pain killers, barbiturics, benzodiazepines, antipsychotics) may produce drowsiness.

Interaction with analytical tests:

If you are to undergo any tests (including blood or urine tests, skin tests with allergens, etc.), notify your doctor that you are taking this medicine, because it may alter the results of such tests.

Pregnancy and breast-feeding

If you are pregnant or are breast-feeding an infant, or if you believe you may be pregnant or plan to become pregnant, consult your doctor or pharmacist before taking this medicine.

Although systemic absorption and passing to breast milk is not foreseen, pregnant and breastfeeding women should consult their doctor before using this medicine.

Driving and using machines

In the approved conditions of use, it is not expected that this medicine have any influence on the ability to drive or use machinery.

3. How to use Neosayomol

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children over 6 years of age:

A small amount of the medicine should be applied to the affected area up to 3-4 times per day. If symptoms persist more than 5 days or if they get worse, stop treatment and consult your doctor.

Children

Children aged 2 to 6:

Children are more prone to the appearance of adverse effects and thus their doctor should be consulted regarding the use of Neosayomol in children between 2 and 6 years of age.

Children younger than 2 years

Do not use in children under 2 years old.

If you take more Neosayomol than you should

Poisoning by Neosayomol is very unlikely given its form of presentation and dose. However, if you apply excessive or very continuous doses you may notice: dryness of skin and mouth, dilated pupils, urine retention, increased heart beat, shaking, speech disorders, psychomotor hyperactivity, sedation and drowsiness. At high doses, coma ataxia (problems with coordination), increased muscular reflexes and convulsions may occur.

If you forget to use Neosayomol

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

Use the dose as soon as possible, or if it is near the next dose, use it at the normal time, following the normal treatment schedule.

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

4. Possible side effects

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

If you feel any side effect that you suffer is serious, or if you notice any side effect not mentioned in this leaflet, inform your doctor or pharmacist.

During the period when diphenhydramine has been used on skin, the following side effects have been reported, although their frequency has not been clearly established:

- The adverse reactions can be allergic, such as hypersensitivity reactions as well as skin reactions (photosensitivity and phototoxicity) such as contact dermatitis, pruritus, exanthemic rash (reddening of the skin) and erythema (swelling of the skin) after intense exposure to sunlight.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Neosayomol

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

Please store below 25°C.

Do not use Neosayomol after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. If you are unsure, ask your pharmacist how to throw away packages and medicines you no longer need. These measures will help to protect the environment.

6. Contents of the package and other information

Composition of Neosayomol

- The active substance is diphenhydramine hydrochloride.
- The other components are glycerol, purified water, menthol, Sepineo P600 (composed by: acrylamide, sodium acryloyldimethyl taurate copolymer, isohexadecane, polysorbate 80 and purified water) isopropyl myristate, calendula oil and sodium hydroxide.

What the product looks like and contents of the package:

This medicine is presented in a tube that contains 30 grammes of cream.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS - Spanish Medicines Agency) website, www.aemps.gob.es/