

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 mucous 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

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Distributor

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This leaflet was approved in February 2012.

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



莎華 -「百癢消」

主要成份：Diphenhydramine hydrochloride

此說明書含有重要資訊，使用此藥物前請細心閱讀此說明書全部內容。

請務必按照本使用者說明書中所描述或按照您的醫生或藥劑師告訴您的方式使用此藥。

- 請保留此說明書，以便可以再次翻閱。
- 如有任何問題，請向您的醫生或藥劑師查詢。
- 如有任何副作用，請諮詢醫生或藥劑師，此包括任何未有在此說明書列出的任何可能的副作用。
- 使用5日後，如果情況沒有好轉或變差，請向醫生諮詢。

這張說明書內包含甚麼資料？

1. 莎華 -「百癢消」是甚麼及用於甚麼情況？
2. 使用莎華 -「百癢消」前您需要留意甚麼？
3. 如何使用莎華 -「百癢消」
4. 可能的副作用
5. 如何貯存莎華 -「百癢消」
6. 包裝及其他資料

1. 莎華 -「百癢消」是什麼及其用途？

莎華 -「百癢消」是一種由抗組胺藥diphenhydramine(苯海拉明)組成的藥膏，有效減輕與過敏有關的痕癢。

莎華 -「百癢消」適用於成年人及6歲以上的兒童，用於緩解過敏性皮膚痕癢或燒灼感的症狀，及由蟲咬、蕁麻疹而引起的痕癢。

2. 使用莎華 -「百癢消」前須知

在以下情況，請勿使用莎華 -「百癢消」

- 如果對莎華 -「百癢消」主要成份diphenhydramine或其他任何成份過敏
- 如果您正在使用含diphenhydramine的藥物或其他可能引起過敏的藥物（抗組胺藥）
- 在未癒合的傷口或感染的皮膚上
- 2歲或以下之小童

警告及注意事項

- 本藥物不適用於傷口、出血、起泡的皮膚或大面積皮膚部位。
- 避免接觸眼睛或其他粘膜。如果出現燒灼感或皮疹或症狀持續，請停止使用本藥物。如有必要，用肥皂和水清洗。
- 為了避免可能出現的光敏反應，您應該保護治療部位免受日光照射。

兒童

6歲以下兒童使用前應先作出評估，因為儘管吸收率低，但它可能會導致皮膚乾燥和口腔乾涸，瞳孔擴張，尿滯留，心跳加速，顫抖，語言障礙，精神運動過度活躍，鎮靜和嗜睡。

65歲以上之人士

65歲以上之人士使用前應先作出評估，因為他們較容易對本藥物可能引起不良的反應。

其他藥物及莎華 -「百癢消」

請告訴您的醫生或藥劑師，如您正使用、最近使用或打算使用其他藥物。

請勿在未諮詢醫生情況下，將其他藥物用於患處，或與已知會對皮膚產生過敏反應(光敏性和光毒性反應)的其他藥物一起使用。

預計不會有高水平的吸收，但部分藥物可能會進入血管，因此，莎華 -「百癢消」與耳毒性藥物(例如某些抗生素)同時使用可能會掩蓋眩暈或頭暈的感覺。

不應在治療過程中飲用酒精飲料，因為同時使用可能會增加鎮靜作用。

莎華 -「百癢消」與抗膽鹼能藥物(例如：抗帕金森病藥，某些抗抑鬱藥，精神鎮定藥及顫茄以及稱為metoprolol的藥物(用於心臟病及降低血壓)同時使用會增加副作用。

莎華 -「百癢消」與鎮靜藥物同時使用可能會產生困倦情況。

與分析測試的相互作用

如果您要接受任何測試(包括血液或尿液測試，致敏原的皮膚測試等)，請通知您的醫生您正在使用此藥，因為這可能會改變此類測試的結果。

懷孕及哺乳期婦女

如您正在懷孕或哺乳期或可能懷孕或計劃懷孕，使用本藥物前請向您的醫生或藥劑師尋求意見。

駕駛及操作機器

按照本說明書正確使用本藥，對駕駛或使用機器不會構成任何影響。

3. 如何使用莎華 -「百癢消」

請務必按照本說明書中所述或按照您的醫生或藥劑師告訴您的方式使用此藥。如您不確定如何使用，請向您的醫生或藥劑師查詢。

建議使用劑量：

成人及6歲以上之兒童

每次將少量藥膏塗於患處，每日最多使用3至4次。

如果症狀持續5天以上或症狀惡化，請立即停止治療並諮詢醫生。

2歲至6歲之兒童

2歲至6歲之兒童比較容易出現不良反應，因此使用莎華 -「百癢消」前應先諮詢醫生。

2歲以下之兒童

切勿用於2歲以下之兒童。

如何使用莎華 -「百癢消」多於您應使用份量

使用莎華 -「百癢消」而導致中毒的情況不大可能。如果您使用過量或持續使用超過指定的劑量，您可能會出現：皮膚和口腔乾燥，瞳孔擴張，尿滯留，心跳加快，顫抖，言語障礙，精神運動過度活躍，鎮靜和嗜睡。使用劑量過高可能引起昏迷(出現協調問題)，可能會增加肌肉反射及驚厥。

假如您忘記使用莎華 -「百癢消」

請勿使用雙倍劑量彌補忘記使用的劑量。

當記起時盡快使用莎華 -「百癢消」，然後在下次使用時按正常時間使用，

如果您對使用此藥有任何疑問，請諮詢您的醫生或藥劑師

4. 可能出現的副作用

像其他藥物一樣，此藥物可能會引起副作用，儘管並不是所有人都會有此情況。

如果您覺得您出現的任何副作用嚴重，或者您發現本說明書中未提及的任何副作用，請通知您的醫生或藥劑師。

使用diphenhydramine(苯海拉明)於皮膚期間，可能會出現以下副作用，但發生的頻率尚未明確確定：

過敏性的不良反應，例如過敏反應以及皮膚反應(光敏性和光毒性反應)如接觸性皮炎，瘙癢症，暴露於日光之下而引起的紅疹和斑點。

如果任何副作用變得嚴重，或者如果您發現本說明書中未列出的任何副作用，請告訴您的醫生或藥劑師。

5. 如何貯存莎華 -「百癢消」

請將藥物存放於兒童不能觸及和視線範圍以外。

請貯存於攝氏25度下。

在標籤和紙盒上註明的有效期後(月/年)切勿使用，有效期所指的是每個月最後一日。

請勿丟棄任何藥物於污水及家居垃圾中，請向您的藥劑師查詢如何棄置不再使用的藥物，這項措施有助保護環境。

6. 包裝及其他資料

莎華 -「百癢消」包含什麼：

主要成份是diphenhydramine hydrochloride

其他成份包括glycerol, purified water, menthol, Sepione P600(composed by acylamide, sodium acryloyldimethyl taurate copolymer, isoheaxadecane, polysorbate 80 and purified water) isopropyl myristate, calendula oil and sodium hydroxide

莎華 -「百癢消」看起來像什麼及包裝

此藥膏裝於膠管內，含量30克。

營銷授權持有人

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代理商

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