

ibufen 5% gel

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 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 a doctor if you do not feel better or if you feel worse after 7 days (5 days in the case of adolescents).

What is in this leaflet

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

1. What Ibufen gel is and what it is used for

Ibufen gel is a gel for cutaneous application (on the skin).

Ibuprofen is an analgesic for external use that affords pain relief.

It is indicated for local symptomatic treatment of occasional muscle and joint pain caused by minor contusions, bumps, strains, torticollis or other contractures, mild sprains caused by a twist, and lumbago.

2. What you need to know before you use Ibufen gel

Do not use Ibufen gel

- if you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6)
- if you have suffered asthma-type allergic reactions (breathing difficulty, breathlessness, bronchospasm, and in certain cases cough or wheezing) when taking aspirin, other analgesics or anti-inflammatory drugs. If you are suffering or have suffered from asthma, rhinitis or urticaria
- in application to open wounds, mucosal membranes or eczematous skin.
- if you are sunburned in the affected area
- in children (under 12 years of age).

Warnings and precautions

- Talk to your doctor or pharmacist before using Ibufen gel.
- This medicine is for use cutaneous use only, do not ingest it.
- Do not apply to broken skin.
- Avoid contact with the mucous membranes (nose, mouth) and the eyes.
- Do not apply the gel to very large areas of skin or for long periods.
- Do not use with tight bandages or apply heat to the area where it is used. If you cover the area where you have used this medicine, do so in such a way that the clothing covering the treated area is slightly loose.
- Do not expose the treated areas to the sun (even when cloudy) or to ultraviolet radiation lamps (UVA rays).

Skin reactions

Serious skin reactions have been reported linked to treatment with Ibufen gel. Stop using Ibufen gel and consult a doctor immediately if you present any skin rash, wounds in the mucous membranes, blistering or other signs of allergy, as these may be the first signs of a very serious skin reaction. See section 4.

Children and adolescents

This medicine must not be used in children under 12 years of age.

Other medicines and Ibufen gel

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

Do not apply other preparations for cutaneous use in the same area of skin where you are using this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

No effect has been reported on the ability to drive vehicles and use machinery when this medicine is used externally on the skin.

3. How to use Ibufen gel

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

If you think the effects of Ibufen gel are too strong or too weak, tell your doctor or pharmacist.

The recommended dose in adults and adolescents aged over 12 years is 3 to 4 applications a day.

How to use Ibufen gel:

This medicine is for external cutaneous use, exclusively on unbroken skin. At first application, you can use the cap to perforate the tube.

Apply the medication gently massaging to help it penetrate, and wash your hands after each application, in order to eliminate any remaining traces of the product.

Do not apply for more than 7 consecutive days.

If you use more Ibufen gel than you should

Cases of intoxication are not likely to occur, as it is only used externally.

In case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

If you forget to use Ibufen gel

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

If you stop using Ibufen gel

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.

- Uncommon (may affect up to 1 in 100 people): in the area of application reddening, inflammation of the skin (dermatitis), local irritation and itching may occur, which disappear when the treatment is suspended.
- Rare (may affect up to 1 in 1,000 people): dermatitis (inflammation of the skin) caused by the sun.
- Not known (frequency cannot be estimated from the available data): generalised red scaly rash, with lumps under the skin and blisters principally located in the folds of the skin, the trunk and the upper extremities, accompanied by fever at the start of the treatment (acute generalised exanthematous pustulosis). The skin becomes sensitive to light. Stop using Ibufen gel if you present these symptoms and seek medical attention immediately. See also Section 2.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibufen gel

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the container after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away containers and medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ibufen gel contains

- The active substance is ibuprofen. Each gram of Ibufen gel contains 50 mg of ibuprofen.
- The other ingredients are levomenthol, carbomers, diisopropanolamine 90%, isopropyl alcohol, glycerol (E-422) and purified water.

What the product looks like and contents of the pack

Ibufen gel is a transparent, colourless or slightly yellowish gel with a menthol aroma.

Ibufen gel is supplied in aluminium tubes containing 50 grams of gel.

Marketing authorisation holder and manufacturer

Laboratorios Cínta, S.A.
Carretera Olaz-Chipi, 10. Polígono Industrial Areta
31620 Huarte (Navarre) - Spain

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莎華®「安立風」消炎止痛軟膏 (Ibufen 5% gel) 50毫克

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內容。

- 請保留此說明書，以便可以再次翻閱。
- 如有任何問題，請向你的醫生或藥劑師查詢。
- 此藥只處方給你，請勿給其他人使用，即使對方病徵跟你相似也可能造成傷害。
- 如有任何副作用，請諮詢你的醫生或藥劑師，此包括任何未有在此說明書列出的任何可能的副作用。請參閱第4節。

此說明書包含甚麼資料？

1. 莎華®「安立風」消炎止痛軟膏是甚麼及用於甚麼情況
2. 使用莎華®「安立風」消炎止痛軟膏前你需要留意甚麼
3. 如何使用莎華®「安立風」消炎止痛軟膏
4. 可能的副作用
5. 如何貯存莎華®「安立風」消炎止痛軟膏
6. 包裝及其他資料

1. 莎華®「安立風」消炎止痛軟膏是甚麼及用於甚麼情況

莎華®「安立風」消炎止痛軟膏是一種用於皮膚應用的凝膠（在皮膚上）。

布洛芬 (Ibuprofen) 是一種外用鎮痛劑，可緩解疼痛，適用於由輕微撞傷、碰撞、扭傷、斜頸或其他韌帶引起的肌肉和關節疼痛。

2. 使用莎華®「安立風」消炎止痛軟膏前你需要留意甚麼

請勿使用莎華®「安立風」消炎止痛軟膏

- 如果您對布洛芬或該藥的任何其他成分過敏（在第6節中列出）
- 如果您在服用阿司匹林、其他鎮痛藥或消炎藥時出現哮喘過敏反應（呼吸困難、呼吸困難、支氣管痙攣，在某些情況下還會出現咳嗽或喘息）。如果您患有或曾經患有哮喘、鼻炎或尋麻疹
- 應用在開放性傷口、黏膜或濕疹皮膚。
- 如果您有癰瘍部位
- 兒童（12歲以下）

警告和注意事項

在使用莎華®「安立風」消炎止痛軟膏之前，請諮詢您的醫生或藥劑師。

- 此藥物僅供皮膚外用，請勿攝入。
- 不適用於破損的皮膚。
- 避免接觸黏膜（鼻子、嘴巴）和眼睛。
- 不要將凝膠塗抹在非常大面積的皮膚上或長時間塗抹。
- 請勿使用過緊的繃帶或將使用此藥物的部位敷敷。
- 如有衣服覆蓋使用藥物的部位，請以稍微寬鬆的衣服覆蓋。
- 不要將治療部位暴露在陽光下（即使是陰天）或紫外線輻射燈（紫外線A）。

皮膚反應

據報導，嚴重的皮膚反應與莎華®「安立風」消炎止痛軟膏治療有關。如果您出現任何皮疹、粘膜炎、起泡或其他過敏跡象，請停止使用莎華®「安立風」消炎止痛軟膏並立即就醫，因為這些可能是非常嚴重的皮膚反應的最初跡象。見第4節。

兒童和青少年

此藥不適用於12歲以下的兒童。

其他藥物和莎華®「安立風」消炎止痛軟膏

如果您正在使用、最近使用或可能使用任何其他藥物，請告訴您的醫生或藥劑師。

不要在同一皮膚區域塗抹其他皮膚用製劑。

懷孕、哺乳和生育

如果您懷孕或哺乳，認為您可能懷孕或計劃生育，請在使用此藥前諮詢您的醫生或藥劑師。

駕駛和使用機器

當此藥外用於皮膚，沒有報導此對駕駛車輛和使用機械的能力有影響。

3. 莎華®「安立風」消炎止痛軟膏的使用方法

請完全按照本說明書中的描述或您的醫生或藥劑師告訴您的方式使用此藥。如果您不確定，請諮詢您的醫生或藥劑師。

如果您認為莎華®「安立風」消炎止痛軟膏的效果太強或太弱，請告訴您的醫生或藥劑師。

成人和12歲以上青少年的建議劑量為每天3至4次。

如何使用莎華®「安立風」消炎止痛軟膏：

此藥供皮膚外用，只適用於沒有破損的皮膚上。第一次使用，您可以使用棉籤給傷口打針。

請用此藥輕輕按摩患處以幫助其滲透，並在每次使用後洗手，以清除皮膚上的殘留。

請不要連續使用超過7天。

如何使用莎華®「安立風」消炎止痛軟膏多於您應使用的劑量

因口供外用，不大可能發生中毒的情況。

如果過量使用或意外攝入，請立即告知你的醫生或藥劑師，並註明藥物名稱和使用份量

假如您忘記使用莎華®「安立風」消炎止痛軟膏

請勿使用雙倍劑量來彌補忘記使用的劑量。

假如您停止使用莎華®「安立風」消炎止痛軟膏

如果您對此藥的使用有任何疑問，請諮詢您的醫生或藥劑師。

4. 可能的副作用

像其他藥物一樣，此藥物可能會引起副作用，儘管並不是每個人都會有此情況。

- 不常見（每100人中最多可能有1個人受影響）：
 - 在應用區域發紅、皮膚發炎（皮炎）、局部刺激和瘙癢可能會出現，當暫停治療時會消失。
- 罕見（每1,000人中最多可能有1個人受影響）：
 - 由太陽引起的皮炎（皮膚炎）。
- 未知（無法從現有數據估計頻率）：
 - 全身性紅色鱗狀皮疹，皮下有腫塊和水疱，主要位於皮膚的褶皺處、軀幹和四肢，治療開始時伴有發燒（急性全身發疹性膿疱病）。皮膚變得對光敏感。如果您出現這些症狀請停止使用莎華®「安立風」消炎止痛軟膏並立即就醫。請參閱第2節。

副作用報告

如果您有任何副作用，請諮詢您的醫生或藥劑師。這包括本說明書中未列出的任何可能的副作用。通過報告副作用，您可以幫助提供有關此藥物安全性的更多信息。

5. 如何貯存莎華®「安立風」消炎止痛軟膏

請將本藥存放於兒童視線範圍以外及不能觸及的地方。

本藥品不需要任何特殊的貯存條件。

在藥盒上「EXP」標明的日期之後，請勿使用此藥。到期日是指該月的最後一天。

請勿通過廢水或家居垃圾丟棄任何藥物。諮詢藥劑師如何丟棄不再使用的藥物。這些措施將有助於保護環境。

6. 包裝及其他資料

莎華®「安立風」消炎止痛軟膏包含什麼：

- 主要成分是布洛芬 (Ibuprofen)。每克莎華®「安立風」消炎止痛軟膏含有50毫克布洛芬 (Ibuprofen)。
- 其他成分是 levomenthol, carbomers, diisopropanolamine 90%, isopropyl alcohol, glycerol (E-422) and purified water.

產品外觀和包裝內容

莎華®「安立風」消炎止痛軟膏是一種透明、無色或微黃色的凝膠，帶有薄荷醇的香氣。

莎華®「安立風」消炎止痛軟膏裝在鋁管內，含量50克。

營銷持有人及製造商

製造商：

BOHM S.A.
Molinaseca, 23. Pol. Ind. Cobo
Calleja 28947 Fuenlabrada
(Madrid) Spain

營銷持有人：

Laboratorios Cinfa, S.A.
Carretera Olaz-Chipi, 10. Poligono Industrial Areta
31620 Huarte (Navarre) - Spain

代理商

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