

## respibien 0.5 mg/ml adultos nasal spray

Oxymetazoline hydrochloride

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

Always take 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 experience 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 3 days.

### What is in this leaflet.

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

### 1. What respibien is and what it is used for

This medicine belongs to the group of medicines known as sympathomimetics. It is a nasal decongestant medicine which contains oxymetazoline as an active substance. Oxymetazoline administered via the nose causes local constriction of the blood vessels, decongesting the nasal mucosa.

It is indicated for local and temporary relief of nasal congestion in adults and children over 6 years of age. You must talk to a doctor if you do not feel better or if you feel worse after 3 days of treatment.

### 2. What you need to know before you take respibien

#### Do not use respibien:

- If you are allergic to oxymetazoline hydrochloride, to other nasal decongestants or any of the other ingredients of this medicine (listed in section 6).
- If you are taking monoamine oxidase inhibitors (MAO inhibitors, used for the treatment of Parkinson's disease and depression). MAO inhibitors may increase the hypertensive effects of oxymetazoline.
- If you have narrow-angle glaucoma.
- If you have recently undergone surgery of the head (if you have suffered any brain, transnasal or transoral surgical procedure).
- If you have inflammation of the skin and mucosa in your nasal vestibule and crusting in your nose (dry rhinitis).
- If you suffer from acute heart disease or cardiac asthma.
- If you have ever suffered from insomnia or vertigo when taking treatment with other sympathomimetic medicines, including, but not limited to any that are used to treat heart disease, hypotension (low blood pressure) or asthma.
- In children under 6 years of age.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking respibien if:

- you have or have had any of the following diseases or symptoms, even if they have only happened once:
  - high blood sugar levels (diabetes mellitus).
  - high blood pressure (arterial hypertension).
  - any disease of the heart or the circulatory system.
  - any prostate disease with difficulty urinating (prostatic hyperplasia).
  - any thyroid disease (hyperthyroidism).

In rare cases, due to its temporary use and when it is used for a long time, oxymetazoline may increase rather than decrease nasal congestion. This is known as a rebound effect.

Rarely, insomnia may occur after using this medicine. If this happens, avoid taking it late in the evening or at night.

Do not exceed the dose recommended in section 3 *How to use respibien*.

To prevent spreading germs, the medicine should not be used by more than one person and the applicator should always be cleaned after each use with a clean, damp cloth.

#### Children

Do not use in children under 6 years of age.

Children may be especially prone to the side effects of this medicine.

#### Other medicines and respibien

Tell your doctor or pharmacist if you are taking, have recently taken or might have to take any other medicines.

This medicine should not be used by people who are taking or have taken any of the following in the last 2 weeks: medicines used to treat depression (tricyclic antidepressants, maprotiline or monoamine oxidase inhibitors (MAOIs)) or a medicine to lower blood pressure called methyldopa.

Also, you should not use it if you are on treatment with phenothiazine (tranquilizer) or medicines to treat asthma.

#### Pregnancy and breastfeeding

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

This medicine should not be used during pregnancy or while breastfeeding.

#### Driving and using machines

Although no problems are expected in this regard, if you feel drowsy, do not drive or use dangerous machines or tools.

#### respibien contains benzalkonium chloride.

This medicinal product contains 0.2 mg of benzalkonium chloride in each ml.

Benzalkonium chloride may cause irritation or inflammation in the nose, especially when used for prolonged periods of treatment.

### 3. How to use respibien

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. If in doubt, ask your doctor or pharmacist.

The recommended dose is:

#### Adults and children over 6 years of age:

1 spray in each nostril, no more than 2 applications in 24 hours.

**Use on children under 6 years of age:** This medicine cannot be used in children under 6 years old (see section 2. Do not take respibien).

#### Older patients (over 65 years of age)

Talk to your doctor or pharmacist as older patients are more sensitive to the side effects of this medicine.

#### How to use

This medicine is for nasal use.

Before applying this medicine, you must eliminate existing nasal fluids by blowing your nose well.

If it is your first time using this product, or if you have not used it for some time, you will need to charge the spray pump. To do this, while holding the container away from your body, press the spray pump several times until a fine mist comes out.

To prevent spreading germs, after each use and before closing the container, clean the applicator tip with a clean, damp cloth. In addition, each container should only be used by 1 person.

If you do not feel better or if you feel worse after 3 days of treatment, stop this treatment and ask your doctor.

#### If you take more respibien than you should

Due to the application of excessive or very continued doses, or if the product is accidentally swallowed, you may notice: headaches, shaking, insomnia, excessive sweating, palpitations, tachycardia, increased blood pressure or sleep disorders.

In children, these effects can include: hallucinations, excitability, urticaria, nausea and vomiting, hysteria, sleepiness or drowsiness, abnormal gait, facial oedema.

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

#### If you forget to take respibien

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

If necessary, take it again as indicated in section 3 *How to use respibien*.

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.

During the period of use of oxymetazoline, the following side effects have been reported, although their frequency has not been clearly established.

The most common side effects are:

Stinging in the application site, dryness, sneezing and irritation of the nose, mouth and throat. Rare side effects are: Anxiety, restlessness, insomnia, hallucinations, tremors, fatigue, irritability and sleep disturbances in children. Tachycardia, palpitations, increased blood pressure. Headache, nausea, skin rash (redness of the skin), inflammation of the nasal mucosa and visual impairment.

Excessive or continuous use of this medicine may lead to rebound nasal congestion.

#### Reporting of side effects

If you experience any type of side effect, consult 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 respibien

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

Please do not store above 25°C.

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. If in doubt, ask your pharmacist how to dispose of the medicines and containers that you no longer need. These measures will help protect the environment.

### 6. Contents of the pack and other information

#### What respibien contains

- The active substance is oxymetazoline hydrochloride. Each ml of solution for nasal spray contains 0.5 mg (65 micrograms per spray) of oxymetazoline hydrochloride.
- The other ingredients are benzalkonium chloride, glycine (E-640), povidone (E-1201), sorbitol non-crystallizable liquid (E-420) and purified water.

#### What the product looks like and contents of the pack

respibien is a colourless or slightly yellowish nasal spray solution. It is presented in white, high density polyethylene bottles, with a dosing pump and a screw cap that guarantees its correct preservation. Each container contains 15 ml of nasal spray solution.

#### Marketing licence holder and manufacturer:

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

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## 莎華 - 「鼻敏敵」噴鼻劑

### 主要成份：Oxymetazoline 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。請參閱第 4 部份
- 如使用 3 日後，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 - 「鼻敏敵」是甚麼及用於甚麼情況？
2. 使用莎華 - 「鼻敏敵」前您需要注意甚麼？
3. 如何使用莎華 - 「鼻敏敵」
4. 可能的副作用
5. 如何貯存莎華 - 「鼻敏敵」
6. 包裝及其他資料

#### 1. 莎華 - 「鼻敏敵」是什麼及其用途？

莎華 - 「鼻敏敵」適用於舒緩因感冒、鼻黏膜炎症引致的鼻塞，及其他鼻腔疾病，如鼻竇黏膜炎症。  
如使用3日後，情況沒有好轉或變差，請向醫生諮詢。

#### 2. 使用莎華 - 「鼻敏敵」前須知

##### 在以下情況，請勿使用莎華 - 「鼻敏敵」

- 如果對莎華 - 「鼻敏敵」主要成份 oxymetazoline hydrochloride 或其他任何 成份過敏 (請參閱本說明書第 6 部份)
- 如果您近期曾進行頭部手術(任何類型的頭顱、經鼻或口腔手術)

##### 警告及注意事項

使用莎華 - 「鼻敏敵」前請先諮詢醫生或藥劑師，假如：

- 您正在接受抗抑鬱藥物治療，phenothiazine(鎮定藥)或 methyl dopa(降血壓藥)
- 如果您患有或曾患有（即使只有一次）以下任何疾病或症狀：
  - 如果您血糖水平過高(糖尿病)
  - 如果您血壓水平過高(高血壓)
  - 如果您有任何心臟或循環系統疾病
  - 如果您有任何前列腺疾病而導致難以排尿(前列腺肥大)
  - 如果您有任何甲狀腺疾病(甲狀腺功能亢進症)
- 如果您在接受其他擬交感神經藥治療時出現失眠或眩暈，例如用於治療心臟病，低血壓或哮喘等的藥物

在罕見的情況下，因此藥效果只是暫時性，長期使用 oxymetazoline 可能會增加鼻塞而不是減少鼻塞，這被稱為反彈效應。

在極少數情況下，使用這種藥物後可能會出現失眠。如果發生這種情況，請避免在傍晚或晚上使用。

不要使用超過說明書第 3 部份中建議的劑量。

為避免傳染，藥物只供一人使用及每次使用後必須以清潔及濕潤的布清潔噴咀。

##### 兒童

12歲以下兒童不適宜使用此藥物。

兒童較容易發生對本藥物的副作用。

##### 其他藥物及莎華 - 「鼻敏敵」

如您正使用、最近使用或打算使用其他藥物，請告訴您的醫生或藥劑師。

在過去的 2 星期內正在服用或曾經服用過以下藥物的患者不應使用本藥：

用於治療抑鬱症的藥物(tricyclic antidepressants 或 monoamine oxidase inhibitors(MAOIs))，或用來降血壓的藥物 methyl dopa。

如使用 phenothiazine (鎮定藥)或任何用於治療哮喘的藥物，也不能使用莎華 - 「鼻敏敵」。

##### 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

儘管使用本藥不會預期有相關於這點的副作用，但如果您感到困倦或頭暈，請勿駕駛或操作工具或重型機器。

##### 莎華 - 「鼻敏敵」中的成份 benzalkonium chloride

這種藥物可能會引起鼻黏膜炎症，特別是用於長期治療時，由於其配方中含有 benzalkonium chloride。如果您懷疑自己有這種反應（持續性鼻塞），則應盡可能使用不含此成份的鼻腔藥物。

#### 3. 如何使用莎華 - 「鼻敏敵」

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

每次每個鼻孔各噴 1 次，24小時內不可使用多於 2 次。

##### 6 歲以下兒童使用

不建議於 6 歲以下之兒童使用

##### 65 歲以上之人士

使用前應諮詢您的醫生或藥劑師，因為他們對本藥物的副作用較敏感。

此藥只適用於鼻腔。

使用本藥前，請先清除鼻孔內的鼻水。

如果您是第一次使用本產品，或一段時間未曾使用過，請先將藥物拿起並與身體保持一定距離，按壓瓶身數次直至有噴霧從噴咀噴出。

為避免傳染，每次使用後必須用濕潤的布清潔噴咀。此外，藥物只供一人使用。

如果使用 3 天後情況未有改善或惡化，請即停止治療並諮詢醫生。

##### 如使用莎華 - 「鼻敏敵」多於您應使用份量

在使用過量或過度使用的情況下，或意外吞服，您可能有以下情況：  
頭痛，顫抖，失眠，出汗過多，心悸，心動過速，血壓升高或睡眠失調。

對於兒童，這些影響可能包括：幻覺，興奮性，蕁麻疹，嘔心和嘔吐，歇斯底里，睡意或嗜睡，步態異常，面部水腫。

如果過量使用或意外吞服，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 - 「鼻敏敵」

請勿使用雙倍劑量彌補忘記使用的劑量。

如有需要，請按照第 3 部份 **如何使用莎華 - 「鼻敏敵」** 繼續使用。

如果您對這該藥物的使用還有其他疑問，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。

在使用 oxymetazoline 的時候，觀察到可能會有以下副作用，但出現的頻率並未確定。

普遍出現的副作用：

使用部位出現刺痛感，乾燥，鼻、口部及喉部痕癢和打噴嚏。

罕見出現的副作用：

焦慮，不安，失眠，幻覺，震顫，疲勞，易怒和兒童睡眠障礙，心動過速，心悸，血壓升高，頭痛，噁心，皮疹（皮膚發紅），鼻黏膜發炎和視力障礙。

過量或長時間使用這種藥物可能會導致鼻塞。

##### 報告副作用

如果你出現任何副作用，請諮詢你的醫生或藥劑師，即使本說明書未列出的可能副作用。通過報告副作用，你可以幫助提供更多有關此藥安全性的信息。

#### 5. 如何貯存莎華 - 「鼻敏敵」

請將藥物存放於兒童不能觸及和視線範圍以外。

請勿貯存於攝氏 25 度以上。

##### 有效日期

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

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 - 「鼻敏敵」包含什麼：

主要成份是 oxymetazoline hydrochloride。每毫升內含 0.5 毫克(每次噴出份量 65 微克) oxymetazoline hydrochloride。其他成份包括 benzalkonium chloride, glycine (E-640), povidone (E-1201), sorbitol non-crystallizable liquid (E-420) 及 purified water。

##### 莎華 - 「鼻敏敵」看起來像什麼及包裝

莎華 - 「鼻敏敵」是一種無色或微黃的液體，作為鼻腔噴劑。  
它裝在白色的高密度聚乙烯瓶中，配有計量泵和確保正確保存的螺旋蓋。  
每個容器內含 15 毫升鼻噴霧溶液。

##### 製造商及營銷持有人

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31620 Huarte (Navarra) - Spain

##### 代理商

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