

# **FLIXONASE AQUEOUS NASAL SPRAY**

## **Fluticasone-propionate**

### **QUALITATIVE AND QUANTITATIVE COMPOSITION**

FLIXONASE Aqueous Nasal Spray (0.05% w/w) is an aqueous suspension of microfine fluticasone propionate for topical administration to the nasal mucosa by means of a metering, atomising spray pump. Each 100 mg of spray delivered by the nasal adaptor contains 50 micrograms of fluticasone propionate.

### **INDICATIONS**

FLIXONASE Aqueous Nasal Spray is indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hayfever and perennial rhinitis. Fluticasone propionate has potent anti-inflammatory activity but when used topically on the nasal mucosa has no detectable systemic activity.

### **DOSAGE AND ADMINISTRATION**

For full therapeutic benefit regular usage is essential. Clinical relevant improvement in symptoms occurs approximately 12 hours after the initial dose. The absence of an immediate effect should be explained to the patient as maximum relief may not be obtained until after three to four days of treatment.

FLIXONASE Aqueous Nasal Spray is for administration by the intranasal route only.

For the prophylaxis and treatment of seasonal allergic rhinitis and perennial rhinitis:

#### **Adults and children over 12 years of age:**

Two sprays into each nostril once a day, preferably in the morning. In some cases two sprays into each nostril twice daily may be required. The maximum daily dose should not exceed four sprays into each nostril.

#### **Children aged 4 to 11 years:**

One spray into each nostril once a day, preferably in the morning. In some cases one spray into each nostril twice daily may be required. The maximum daily dose should not exceed two sprays into each nostril.

#### **Elderly:**

The normal adult dosage is applicable.

### **CONTRA-INDICATIONS**

FLIXONASE Aqueous Nasal Spray is contraindicated in patients with a hypersensitivity to any of its ingredients.

### **WARNINGS AND PRECAUTIONS**

Local infection: Infections of the nasal airways should be appropriately treated but do not constitute a specific contraindication to treatment with intranasal fluticasone propionate.

Care must be taken when withdrawing patients from systemic steroid treatment, and commencing therapy with intranasal fluticasone propionate, particularly if there is any reason to suspect that their adrenal function is impaired.

Systemic effects with nasal corticosteroids have been reported, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.

Reduced growth velocity has been observed in children treated with intranasal corticosteroids. Therefore, children should be maintained on the lowest dose which achieves adequate symptom control.

During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side-effects (see *Interactions*).

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes, which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

The full benefit of FLIXONASE Aqueous Nasal Spray may not be achieved until treatment has been administered for several days.

Although FLIXONASE Aqueous Nasal Spray will control seasonal allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may in certain instances necessitate appropriate additional therapy.

## **INTERACTIONS**

Under normal circumstances, very low plasma concentrations of fluticasone propionate are achieved after intranasal dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome P450 3A4 in the gut and liver. Hence, clinically significant drug interactions mediated by fluticasone propionate are unlikely.

A drug interaction study in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can greatly increase fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post-marketing use, there have been reports of clinically significant drug interactions in patients receiving intranasal or inhaled fluticasone propionate and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of fluticasone propionate and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects.

Studies have shown that other inhibitors of cytochrome P450 3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to fluticasone propionate without notable reductions in serum cortisol concentrations. Nevertheless, care is advised when co-administering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole), as there is potential for increased systemic exposure to fluticasone propionate.

## **PREGNANCY AND LACTATION**

As with other drugs, the use of intranasal fluticasone propionate during pregnancy and lactation requires that the benefits be weighed against possible risks associated with the product or with any alternative therapy.

There is inadequate evidence of safety in human pregnancy. In animal reproduction studies adverse effects typical of potent corticosteroids are only seen at high systemic exposure levels; direct intranasal application ensures minimal systemic exposure.

The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the breast milk. However plasma levels in patients following intranasal application of fluticasone propionate at recommended doses are likely to be low.

### **EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

Fluticasone propionate is unlikely to produce an effect.

### **ADVERSE REACTIONS**

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  and  $< 1/10$ ), uncommon ( $\geq 1/1000$  and  $< 1/100$ ), rare ( $\geq 1/10,000$  and  $< 1/1000$ ) and very rare ( $< 1/10,000$ ) including isolated reports and not known (cannot be estimated from the available data). Very common, common and uncommon events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data. In assigning adverse event frequencies, the background rates in placebo groups were not taken into account, since these rates were generally comparable to those in the active treatment group.

#### **Immune system disorders**

Very rare: Hypersensitivity reactions, anaphylaxis/anaphylactic reactions, bronchospasm, skin rash, oedema of the face or tongue.

#### **Nervous system disorders**

Common: Headache, unpleasant taste, unpleasant smell.  
As with other nasal sprays, unpleasant taste and smell and headache have been reported.

#### **Eye disorders**

Very rare: Glaucoma, raised intraocular pressure, cataract.

#### **Respiratory, thoracic and mediastinal disorders**

Very common: Epistaxis.  
Common: Nasal dryness, nasal irritation, throat dryness, throat irritation.  
As with other intranasal products, dryness and irritation of the nose and throat, and epistaxis have been reported.  
Very rare: Nasal septal perforation  
Not known: Nasal ulcers.  
Nasal septal perforation has been reported following the use of intranasal corticosteroids.

### **OVERDOSE**

There are no data from patients available on the effects of acute or chronic overdosage with intranasal fluticasone propionate. In healthy volunteers, intranasal administration of 2 mg fluticasone propionate twice daily for seven days had no effect on hypothalamic-pituitary-adrenal (HPA) axis function.

Administration of doses higher than those recommended over a long period of time may lead to temporary suppression of adrenal function.

In these patients, treatment with fluticasone propionate should be continued at a dose sufficient to control symptoms; adrenal function will recover in a few days and can be monitored by measuring plasma cortisol.

### **List of excipients**

Dextrose (anhydrous), Microcrystalline Cellulose and Carboxymethylcellulose Sodium, Phenylethyl Alcohol, Benzalkonium Chloride, Polysorbate 80, Dilute Hydrochloric Acid, Purified Water

**STORAGE**

Store as directed on the outer package.

Version number: HK082018(GDS29/IPI08)

Trade marks are owned by or licensed to the GSK group of companies  
© 2018 GSK group of companies or its licensor

## INFORMATION FOR THE PATIENT 患者須知

### 1. What is FLIXONASE Aqueous Nasal Spray?

FLIXONASE Aqueous Nasal Spray is indicated for the prophylaxis and treatment of seasonal allergic rhinitis including hayfever and perennial rhinitis.

### 1. 甚麼是輔舒良水性鼻用噴霧劑？

輔舒良水性鼻用噴霧劑是用於預防及治療季節性的敏感鼻炎，如枯草熱及常年性鼻炎。

### 2. Before you use FLIXONASE Aqueous Nasal Spray

#### Do not use Flixonase if:

- You are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

#### Warnings and precautions

Talk to your doctor or pharmacist before using Flixonase:

- If you have ever had an operation on your nose.
- If you have an infection in your nose

Contact your doctor if you experience blurred vision or other visual disturbances.

#### Other medicines and Flixonase

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Check with your doctor or pharmacist before using your medicine if:

- you have had steroids for a long time, either as an injection or by your mouth
- you are taking a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may wish to monitor you carefully if you are taking these medicines
- you are taking certain medicines used to treat fungal infections (e.g. ketoconazole)

#### Taking Flixonase with food and drink

You can use Flixonase at any time of day, with or without food.

#### Pregnancy and breast-feeding

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

#### Driving and using machines

Flixonase is not likely to affect you being able to drive or use any tools or machines.

#### Flixonase contains benzalkonium chloride

Benzalkonium chloride may cause problems with your breathing (bronchospasm).

### 2. 使用輔舒良水性鼻用噴霧劑前須知

如有以下情況，切勿使用輔舒良：

- 你對 fluticasone propionate 或此藥的任何其他成分（在第 6 部分中列出）過敏。

#### 警告及注意事項

在使用輔舒良之前，請諮詢您的醫生或藥劑師：

- 你的鼻子曾經歷過手術。
- 你的鼻子受感染。

如您出現視力模糊或其他視力障礙，請諮詢您的醫生。

### 其他藥物及輔舒良

如果你正在使用，或最近使用過任何其他藥物，請告知你的醫生，這包括通過非處方途徑獲得的藥物，包括草本藥物。

如果出現以下情況，請在使用藥物前諮詢醫生或藥劑師：

- 你長時間服用類固醇，不論是注射還是口服
- 你正在服用一種叫做蛋白酶抑制劑（如 Ritonavir）的抗病毒藥物的產品或可能增加 fluticasone propionate 作用如含有 Cobicistat 的產品。如果您正在服用這些藥物，您的醫生可能希望仔細監測您。您的醫生可能希望您能對你進行仔細監測。
- 您正在服用某些用於治療真菌感染的藥物（如 ketoconazole）

### 懷孕及哺乳

如果您正在懷孕或哺乳，認為您可能懷孕或計劃生孩子，請在服用此藥前諮詢醫生。

### 駕駛及使用機器

輔舒良不太可能會對你駕車或使用任何工具或機器造成影響。

### 輔舒良含有 benzalkonium chloride

Benzalkonium chloride 可能會導致呼吸問題（支氣管痙攣）。

## 3. How to use FLIXONASE Aqueous Nasal Spray

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

- **Do not use in children under 4 years old.**
- **FLIXONASE Aqueous Nasal Spray should only be used in the nose.**
- **It may take a few days for FLIXONASE to work fully and it is important that you use FLIXONASE regularly. DO NOT STOP TREATMENT even if you feel better, unless you are told to do so by your doctor.**
- Use the spray everyday

If your symptoms are no better or get worse after regular treatment then consult your doctor.

**Adults and children over 12 years of age:** Two sprays into each nostril once a day, preferably in the morning. In some cases two sprays into each nostril twice daily may be required. The maximum daily dose should not exceed four sprays into each nostril.

**Children aged 4 to 11 years:** One spray into each nostril once a day, preferably in the morning. In some cases one spray into each nostril twice daily may be required. The maximum daily dose should not exceed two sprays into each nostril.

### 3. 如何使用 輔舒良 水性鼻用噴霧劑

- 不要對 4 歲以下兒童使用。
- 輔舒良 水性鼻用噴霧劑只適合於鼻內途徑應用。
- 輔舒良 可能需要數天才會充分地產生效用，所以繼續使用它，即使你可能不會馬上感覺好些。
- 每天使用此噴霧劑。

若您發覺在定時用藥後情況並沒改善，又或病況即時變差，應諮詢您的醫生。

**成人和 12 歲以上兒童：**每天於每個鼻孔噴入 2 次劑量，早上時段使用較佳。某些情況若有需要，可每天 2 次於每個鼻孔噴入 2 次劑量。每天最高不可超過每個鼻孔 4 次的劑量。

**4-11 歲兒童:** 每天於每個鼻孔噴入 1 次劑量，早上時段使用較佳。某些情況若有需要，可每天 2 次於每個鼻孔噴入 1 次劑量。每天最高不可超過每個鼻孔 2 次的劑量。

**If you use more Flixonase than you should**

Tell your doctor as soon as possible if you accidentally take a larger dose than you were told to. It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

**如使用了過多的輔舒良**

若您意外地服用超過所建議的劑量，您應盡早通知您的醫生。

必須按照藥劑師的標籤或醫生建議用藥。你應只服用醫生推薦的; 使用更多或更少可能會使您的症狀惡化。

**If you forget to use Flixonase**

If you miss a dose just take the next dose when it is due.

**如忘記使用輔舒良** 若您忘記服藥，您只需等至服用下一劑量的時間，依照平常的服藥時間繼續服藥。

**If you stop taking Flixonase 如你停止使用輔舒良**

Do not stop treatment even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back.

即使你感到有所好轉，也不要停止用藥，除非醫生要求你停止用藥。如果你停止用藥，症狀可能會重現。

如你對用藥還有任何進一步的疑問，請諮詢你的醫生或藥劑師。

**4. What are the common side effects of FLIXONASE Aqueous Nasal Spray?**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Allergic reactions: get a doctor's help straight away**

A small number of people get allergic reactions to Flixonase, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- becoming very wheezy, coughing or having difficulty with breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face, mouth or tongue
- skin rashes or redness

**If this happens, tell your doctor straight away – you may need urgent medical treatment.**

Allergic reactions to Flixonase are very rare (These affect less than 1 in 10,000 people).

**Immediately after you use your spray**

- You may sneeze a little, but this soon stops.
- Very occasionally you may find you get an unpleasant taste or smell.

**Tell your doctor as soon as possible if you notice any of the following side effects:**

**Other side effects include:**

**Very common** (may affect more than 1 in 10 people)

- Nose bleeds.

**Common** (may affect up to 1 in 10 people)

- Headache.

- Unpleasant taste.
- Unpleasant smell.
- A dry or painful nose or throat.

**Very rare** (may affect up to 1 in 10,000 people)

- Skin reaction – which can range from red, itchy rash and blotches to a more severe skin reaction such as dry, cracked and peeling skin.
- Problems with your eyes such as pain or blurred vision.
- Damage to your nose

**Not known:** frequency cannot be estimated from the available data

- Blurred vision
- Sores in the nose

Very rarely, the normal production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms. In children this side effect can rarely cause them to grow more slowly than others. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.

#### **4. 輔舒良水性鼻用噴霧劑有甚麼常見副作用？**

與所有藥物一樣，此藥亦有可能會引起副作用，雖然並非每個人都會出現副作用。以下是本藥物可能會引發的副作用：

##### **過敏反應：立即尋求醫生協助**

少數人會對輔舒良產生過敏反應。如果沒有治療，就會發展成更加嚴重，甚至危及生命的問題。症狀包括：

- 發出明顯的喘鳴聲，咳嗽或呼吸困難
- 突然感到虛弱或頭暈（可能倒下或喪失意識）
- 面部，嘴部或舌頭腫脹
- 皮膚紅疹或發紅

如果出現這種情況，請立即告知你的醫生——你可能需要接受緊急治療。

對輔舒良出現過敏反應是非常罕見（這可能會影響 10000 人中最多 1 人）

##### **在使用噴霧後立即出現**

- 可能打噴嚏，但很快停止。
- 偶爾，你會嘗到或聞到難聞的味道

如果你注意到以下任何副作用，請立即告知你的醫生：

**十分常見**（這可能會影響 10 人中多於 1 人）

- 流鼻血

**常見**（這可能會影響 10 人中最多 1 人）

- 頭痛
- 難聞的味道
- 難聞的氣味
- 鼻子或喉嚨發乾或疼痛

**十分罕見**（這可能會影響 10000 人中最多 1 人）



- 皮膚反應 - 從紅色，發癢的皮疹和斑點到更嚴重的皮膚反應，如皮膚乾燥，破裂和脫皮
- 眼睛出現問題，如疼痛或視力模糊
- 鼻子受損

未知：無法從可用數據估計頻率

- 視野模糊
- 鼻瘡

極少數情況下，正常的體內類固醇製造可能會受到影響。如長時間使用高劑量類固醇，這種情況更有可能發生。您的醫生將確保您使用控制症狀的最低劑量的類固醇來幫助阻止這種情況發生。在兒童中，這種副作用很少會使他們比其他人生長得更慢。長期接受這種治療的兒童將由醫生定期檢查他們的身高。

#### **報告副作用**

如果你出現了任何副作用，請諮詢你的醫生、藥劑師或護士。這包括未被列入本單張中的任何可能的副作用。

通過報告副作用，您可以幫助提供更多有關此藥的安全性信息。

## **5. INSTRUCTIONS FOR USE/HANDLING**

### **5. 使用/處理方法**

The spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray. A new spray (or one that has not been used for a few days), may not work first time so you will need to prepare the nasal spray following the instructions under 'Preparing the nasal spray'.

噴霧劑的塵蓋是用來保護噴嘴及保持其清潔，使用噴霧劑前請將塵蓋拔去。如這是一瓶新的噴霧劑或噴霧劑有數天未被使用，它未必能立即使用，請按照以下“準備噴霧劑”的指示為您的噴霧劑“作準備”。

## Preparing the nasal spray

### 準備噴霧劑

You must prepare the nasal spray:

在下列情況下您必須為您的噴霧劑“作準備”：

- Before you use it for the first time 第一次使用前。
- If you have not used it for a few days 噴霧劑有數天未被使用。
- If you have just cleaned it following the instructions under ‘Cleaning the nasal spray’. 您剛剛按照“清洗噴霧劑”的指示完成清潔噴霧劑。

Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

替噴霧劑“作準備”可確保您能獲得完整的劑量。請按照以下指示：

- Shake the nasal spray and remove the dust cap by gently squeezing the ribbed sides with your forefinger and thumb and pulling it straight off. Do not twist it off. **(picture 1)**

搖勻噴霧劑，用食指及拇指輕按噴霧劑兩側，將塵蓋垂直拔出。切勿將塵蓋擰下來。(圖1)

- Hold the nasal spray upright and point the nozzle away from you.

垂直持著瓶子，但使噴霧劑指離您。

- Put your forefinger and middle finger on the collar either side of the nozzle and put your thumb underneath the bottle. **(picture 2)**

以食指及中指握緊噴嘴兩邊，拇指在瓶底。(圖2)

- Keep your thumb still, and press down firmly on the collar with your fingers to release a fine spray into the air. **(picture 2)**

保持拇指穩定，用食指及中指按下噴咀，噴霧應以薄霧狀釋出。(圖2)

- The nasal spray is now ready for use.

噴霧劑現在已準備妥當可以使用。

- If you think the nozzle may be blocked, don't use a pin or anything sharp to clear it.

若您認為噴霧劑被堵塞，切勿用針或其他尖銳物件疏通噴霧劑。

- Try to clean it by following the instructions under “Cleaning the nasal spray”.

請參考“清洗噴霧劑”來嘗試清洗您的噴霧劑。



Picture 1 / 圖1



Picture 2 / 圖2

## Using the Spray 使用噴霧劑

1. Shake the nasal spray and remove the dust cap.  
輕輕搖勻瓶子及拔去塵蓋。



Picture 3a / 圖 3a

2. Blow your nose to clear your nostrils.  
輕輕擤清鼻子。

3. Close one nostril with your finger and carefully place the nozzle in the other nostril. Tilt your head forward a little bit and hold the nasal spray upright. (picture 3a and 3b)  
用手指按住一邊鼻孔，將噴嘴小心地插入另一邊鼻孔。頭稍向前傾並保持瓶子垂直。(圖 3a 及 3b)



Picture 3b / 圖 3b

4. As you breathe in through your nose, press down firmly on the collar with your fingers. (picture 3a and 3b)  
當您開始用鼻吸氣時，用手指按壓噴嘴。(圖 3a 及 3b)

5. Breathe out through your mouth  
用口呼氣。

6. Repeat steps 3 to 4 for your other nostril.  
在另一邊鼻孔重覆步驟 3 至 4。



Picture 4 / 圖 4

7. After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief.  
使用噴霧劑後，用清潔的紙巾或手帕小心擦淨噴嘴。

8. Replace the dust cap (picture 4)  
套回塵蓋。(圖 4)

## Cleaning the Spray 清洗噴霧劑

You must clean your nasal spray at least once a week to stop the nozzle from blocking up. Follow these steps:

您應每週最少清潔您的噴霧劑一次以避免噴嘴堵塞。請按照以下指示：

- Remove the dust cap. 拔去塵蓋。
- Remove the nozzle by pulling upwards on the collar. (picture 5) 從瓶身向上拔出噴嘴。(圖 5)
- Soak the nozzle and dust cap in warm water for a few minutes. 將噴嘴和塵蓋浸入溫水幾分鐘。
- Then rinse under a running tap. 然後在水喉下沖洗。
- Shake off the excess water and let them dry in a warm place. 去掉多餘水份並將噴嘴和塵蓋放在溫暖的地方自然風乾。
- Put the nozzle back on the spray. 套回塵蓋。

Prepare the nasal spray following the instructions under 'Preparing the nasal spray' so that it is ready for use.

請按照“準備噴霧劑”的指示為您的噴霧劑“作準備”來使用。



Picture 5 / 圖 5

## 6. Contents of the pack and other Information

### What Flixonase Aqueous Nasal Spray contains

- The active substance is fluticasone propionate
- The other ingredients are cellulose microcrystalline, carmellose sodium, glucose, polysorbate 80, water purified and the preservatives benzalkonium chloride and phenylethyl alcohol. These other ingredients are needed to make a stable suspension which will not go off.

## 6. 包裝上的資訊以及其他內容

### 輔舒良水性鼻用噴霧劑包含哪些成分

- 活性物質為 fluticasone propionate
- 其他成分為 Dextrose (anhydrous), Microcrystalline Cellulose and Carboxymethylcellulose Sodium, Phenylethyl Alcohol, Benzalkonium Chloride, Polysorbate 80, Dilute Hydrochloric Acid, Purified Water。

Version number: HK082018(GDS29/UKPIL20180313)

版本編號：HK082018(GDS29/UKPIL20180313)

Trade marks are owned by or licensed to the GSK group of companies  
© 2018 GSK group of companies or its licensor.

商標為葛蘭素史克集團擁有或經授權使用。

©2018 葛蘭素史克集團或其授權人。