BECONASE Aqueous Nasal Spray

1. Name of the medicinal product
BECONASE Aqueous Nasal Spray

2. Qualitative and quantitative composition
Beclomethasone Dipropionate 50micrograms (as monohydrate, micronised)

Excipient with known effect:
Benzalkonium Chloride
For the full list of excipients, see section 5.1

3. Pharmaceutical form
Aqueous suspension for intranasal inhalation via metered dose atomising pump.

4. Clinical particulars
4.1 Therapeutic indications
Prophylaxis and treatment of perennial and seasonal allergic rhinitis and vasomotor rhinitis.

4.2 Posology and method of administrationBECONASE is for administration by the intranasal route only.

Adults and children over 6 years of age:
The recommended dosage is two sprays into each nostril twice daily.
A dosage regimen of one application into each nostril three or four times daily may be preferred.
Total daily administration should not normally exceed 8 sprays (400 micrograms).
For full therapeutic benefit regular usage is essential.
The co-operation of the patient should be sought to comply with the regular dosage schedule and it should be explained that maximum relief may not be obtained within the first few applications.

For children under six years old, there are insufficient clinical data to recommend use.

4.3 Contraindications
Hypersensitivity to the active substance or any of the excipients listed in section 5.1.

4.4 Special warnings and precautions for use
Systemic effects of nasal corticosteroids may occur, 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. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses. It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid, if possible to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist.

Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

Care must be taken while transferring patients from systemic steroid treatment to BECONASE Aqueous Nasal Spray if there is any reason to suppose that their adrenal function is impaired.

Infections of the nasal passages and paranasal sinuses should be appropriately treated but do not constitute a specific contra-indication to treatment with BECONASE Aqueous Nasal Spray.

Although BECONASE 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 particularly to control eye symptoms.

BECONASE Aqueous Nasal Spray contains Benzalkonium Chloride which may cause bronchospasm.

Visual Disturbance
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.

4.5 Interaction with other medicinal products and other forms of interaction
Beclomethasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

4.6 Pregnancy and lactation

Pregnancy
There is inadequate evidence of safety of BECONASE in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. It should be noted, however, that the foetal changes in animals occur after relatively high systemic exposure. BECONASE Aqueous Nasal Spray delivers beclomethasone dipropionate directly to the nasal mucosa and so minimises systemic exposure.
The use of beclomethasone dipropionate should be avoided during pregnancy unless thought essential by the doctor.

Lactation
No specific studies examining the transference of beclomethasone dipropionate into the milk of lactating animals have been performed. It is reasonable to assume that BECONASE is secreted in milk but at the dosages used for direct intranasal administration, there is low potential for significant levels in breast milk. The use of beclomethasone dipropionate in mothers breast feeding their babies requires that the therapeutic benefits of the drug be weighed against the potential hazards to the mother and baby.

4.7 Effects on ability to drive and use machines
Not relevant

4.8 Undesirable effects
Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common, common and uncommon reactions were generally determined from clinical trial data. Rare and very rare reactions were generally determined from spontaneous data. In assigning adverse reaction 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.

System Organ Class	Adverse Event	Frequency
Immune system disorders	Hypersensitivity reactions including:	
	Rash, urticaria, pruritis, erythema	Common
	Angioedema	Very rare
	Dyspnoea and/or bronchospasm	Very rare
	Anaphylactoid/anaphylactic reactions	Very rare
Nervous system disorders	Unpleasant taste, unpleasant smell	Common
Eye disorders	Glaucoma, raised intraocular pressure, cataract	Very rare

	Vision, Blurred (see also section 4.4)	Not known
Respiratory, Thoracic & Mediastinal disorders	Epistaxis, nasal dryness, nasal irritation, throat dryness, throat irritation.	Common
	Nasal septum perforation.	Very rare

Systemic effects of nasal corticosteroids may occur particularly when used at high doses for prolonged periods.

4.9 Overdose

The only harmful effect that follows inhalation of large amounts of the drug over a short time period is suppression of Hypothalamic-Pituitary-Adrenal (HPA) function. No special emergency action need be taken. Treatment with BECONASE Aqueous Nasal Spray should be continued at the recommended dose. HPA function recovers in a day or two.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

There is no specific treatment for an overdose of BECONASE. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

5. Pharmaceutical particulars
5.1 List of excipients
Microcrystalline cellulose
Carboxymethylcellulose sodium
Glucose anhydrous
Polysorbate 80
Purified Water
Benzalkonium chloride
Phenylethyl alcohol
Dilute hydrochloric acid

5.2 Storage
Store as directed on the outer package.
Discard three months after first using the spray.
5.3 Special precautions for disposal and other handling
Refer to Patient Information Leaflet.

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BECONASE Aqueous Nasal Spray – Patient Information Leaflet

1. What BECONASE is and what it is used for

BECONASE Aqueous Nasal Spray (called 'BECONASE' in this leaflet) contains a medicine called beclomethasone dipropionate. This belongs to a group of medicines called steroids (also called 'cortico-steroids').

- steroids work by reducing inflammation.
- they reduce swelling and irritation in your nose.
- this helps to relieve itching, sneezing and your blocked or runny nose.

BECONASE is used to prevent and treat:

- inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as Hayfever.
- inflammation in the lining of your nose (rhinitis) due to year round (perennial) allergies, such as animal allergies.

2. What you need to know before you use BECONASE

Do not use BECONASE if:

- you are allergic to beclomethasone dipropionate or any of the other ingredients of this medicine (listed in section 6).

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

Other medicines and BECONASE

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

Some medicines may increase the effects of BECONASE and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

If you are unsure if the above apply to you, talk to your doctor or pharmacist before using BECONASE.

BECONASE with food and drink

You can use BECONASE 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 or pharmacist for advice before taking this medicine.

Driving and using machines

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

BECONASE contains benzalkonium chloride

BECONASE contains benzalkonium chloride which may cause problems with your breathing (bronchospasm)

3. How to use BECONASE

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 6 years old.**
- **It takes a few days for this medicine to work. So keep using it, even though you may not feel better straight away.**
- You should use the spray every day.

How much to use - adults and children (aged 6 and over)

- The usual starting dose is 2 sprays into each nostril twice a day.
- The most you would use in over 24 hours is normally 8 sprays (4 sprays per nostril).
- Do not use a larger dose or use your nasal spray more often than your doctor tells you.

If you use high doses of BECONASE

There are times when your doctor may need to adjust the dose of the steroid you are given or the way in which you take it. These times are:

- times of extreme stress.
- during admission to hospital after a serious accident, injury or illness.
- before and after a surgical operation.

If you think that any of these apply to you whilst using BECONASE, speak to your doctor or pharmacist.

If you forget to use BECONASE
If you miss a dose, just use the next dose when it is due.

If you use more BECONASE than you should
Tell your doctor if you use more 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.

If you stop taking BECONASE
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.

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. 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 BECONASE, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- becoming very wheezy or having difficulty with breathing
- swelling around the face or throat

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

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:

Common (may affect up to 1 in 10 people)
- A dry or painful nose or throat.
- Bad nose bleeds.
- Mild allergic reactions including skin rashes or redness, itching or weals like nettle rash or hives.

Very rare (may affect up to 1 in 10,000 people)
- Damage to your nose
- Cloudy lens in the eye (cataract)
- Increased pressure in the eye (glaucoma)

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.

Not Known: frequency cannot be estimated from the available data
- Blurred vision (see Section 2 – Do not use BECONASE if)

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 the leaflet.

5. How to store BECONASE
- Store as directed on the outer package.
- Stop using this bottle three months after you first opened it.

6. Contents of the pack and other Information
What BECONASE Aqueous Nasal Spray contains
- The active substance is beclomethasone dipropionate
- The other ingredients are microcrystalline cellulose, carboxymethylcellulose sodium, glucose anhydrous, polysorbate 80, purified water, benzalkonium chloride, phenylethyl alcohol and dilute hydrochloric acid. These other ingredients are needed to make a stable suspension which will not go off.

What BECONASE Aqueous Nasal Spray looks like and contents of the pack
Each bottle delivers 200 sprays. Each spray contains 50 micrograms of beclomethasone dipropionate.

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BECONASE 水性鼻用噴霧劑——患者資訊單張

1. 什麼是 BECONASE 及其用途

BECOANSE 水性鼻用噴霧劑（在本單張中稱為“BECONASE”）含有名為 beclomethasone dipropionate 的藥物。它屬於一組名為類固醇的藥物（也被稱為‘皮質類固醇’）。

- 類固醇通過減少炎症發揮藥效。
- 它們能減輕鼻腔內的腫脹和刺激。
- 這有助於減輕痕癢、噴嚏以及鼻塞或流鼻涕的症狀。

BECONASE 被用於防治：

- 由於季節性過敏導致的鼻內炎症，例如花粉熱。
- 由於全年（終年的）過敏導致的鼻內炎症，例如動物過敏。

2. 使用 BECONASE 前需要瞭解的資訊

如有以下情況，切勿使用 BECONASE：

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

如你出現視線模糊或其他視覺干擾的情況，請聯絡你的醫生

其他藥物及 BECONASE

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。

有些藥物或會增加 BECONASE 的效果。如果你正在使用這些藥物（包括一些治療 HIV 的藥物: ritonavir, cobicistat）你的醫生可能希望能對你進行仔細監測。

如存在以下情況，請在用藥前與你的醫生或藥劑師確認：

- 你已通過注射或口服的方式，長期使用類固醇。
- 你的鼻子曾經歷過手術。
- 你的鼻子受感染。

如果你不確定上述情況對你是否適用，請在使用 BECAONSE 前諮詢你的醫生或藥劑師。

BECONASE 與食物和飲品

你可以在一天中的任何時間使用 BECONASE，BECONASE 可與食物一同使用，也可分開使用。

懷孕和哺乳

如果你已懷孕或正在哺乳，認為自己可能懷孕或計劃懷孕，請在使用本藥物前諮詢你的醫生或藥劑師。

駕駛及使用機器

BECONASE 不太可能會對你駕車或使用任何工具或機器造成影響。

BECONASE 含有 benzalkonium chloride

BECONASE 含有 benzalkonium chloride，這可能會造成呼吸問題（支氣管痙攣）

3. 如何使用 BECONASE

請遵照醫囑用藥。如果不確定，請向你的醫生或藥劑師諮詢。

- **不要對 6 歲以下兒童使用。**
- **本藥物需要數天時間發揮藥效。因此，請持續用藥，即使你並沒有立即感覺到好轉。**
- 你應每天使用此噴霧劑。

用藥劑量——成人和兒童（6 歲及以上）

- 通常的初始劑量為每邊鼻孔各噴兩下，每日兩次。
- 24 小時內，最大使用劑量通常為 8 噴（每個鼻孔 4 噴）。
- 用藥不要超出醫生規定的劑量或次數。

如你使用高劑量的 BECONASE

有時，你的醫生會調整處方的類固醇劑量或你使用類固醇的方式：

- 在面臨極度壓力時
- 在發生嚴重事故、受傷或發病後的住院期間
- 在手術前和手術後

如你認為自己在使用 BECONASE 時，符合上述任何情況，請諮詢你的醫生或藥劑師。

如忘記使用 BECONASE

如你忘記用藥，只需在下次用藥時正常用藥便可。

如使用了過多的 BECONASE

假如您使用過量，請告知你的醫生。

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。

如你停止使用 BECONASE

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. 可能出現的副作用

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 BECONASE 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，或呼吸困難
- 面部或喉嚨腫脹

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。

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：

常見（這可能會影響 10 人中最多 1 人）

- 鼻子或喉嚨發乾或疼痛
- 嚴重的流鼻血
- 溫和的過敏反應，包括皮膚紅疹或發紅，痕癢或出現像風疹或蕁麻疹一樣的斑痕。

十分罕見（這可能會影響 10000 人中最多 1 人）
- 鼻子受損
- 眼中出現模糊(白內障）
- 眼壓升高（青光眼）

在極為罕見的情況下，你體內產生類固醇的正常機制會受到影響。如果你長期大劑量用藥，就有可能出現這種情況。你的醫生會確保在控制症狀的情況下使用最低劑量的類固醇，從而防止這種情況的出現。在兒童中，這種副作用會罕見地讓他們比同齡人生長更加緩慢。長期接受這種治療的兒童需要由醫生定期檢查他們的身高。

未知：無法從現有數據中預估頻率
- 視覺模糊（見第2部分——如有以下情況，請勿使用BECONASE）

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。

5. 如何儲存 BECONASE
- 按照外包裝上的說明儲存。
- 在你首次打開瓶子 3 個月後，請停止使用此瓶藥物。

6. 包裝上的資訊以及其他內容
BECONASE 水性鼻用噴霧劑包含哪些成分
- 活性物質為 beclomethasone dipropionate
- 其他成分為 microcrystalline cellulose，carboxymethylcellulose sodium，glucose anhydrous，polysorbate 80，purified water，benzalkonium chloride, phenylethyl alcohol 和 dilute hydrochloric acid。

BECONASE 水性鼻用噴霧劑的外觀和包裝內容
每瓶含量為 200 劑。每劑含 50 微克 beclomethasone dipropionate。
版本編號：HK062020(GDS18/emc20180123)

How to use Beconase Aqueous Nasal Spray

如何使用鼻可靈水性鼻用噴霧劑

1 Before using, gently blow your nose to clear your nostrils and remember that, unless otherwise directed by your doctor, the usual dosage is **two sprays in each nostril twice daily.**

使用前，先把鼻孔清理乾淨，並記住一般劑量是**每邊鼻孔各噴兩下，每天兩次**，或遵照醫生指示。

2 To prepare for use, first shake the bottle, then remove the dust cap and hold as shown. If you are using for the first time or have not used the spray for a week or more, test by spraying into the air until the jet appears as a fine mist. Do this by pressing downwards on the white collar with the forefinger and middle finger using your thumb to support the base of the bottle.

噴時，先搖勻藥瓶，然後拿開防塵蓋，將藥瓶如圖拿著。如果是第一次使用，或一個星期以上沒使用噴霧劑，就要把噴霧向空中試噴，直至出現微細的噴霧，具體做法是用食指和中指按下白項圈，並用拇指托住瓶底。

3 To use, close one nostril by placing your finger over the opening. Insert the nosepiece into the other nostril. Then, whilst gently breathing in, press downwards on the white collar with the forefinger and middle finger using your thumb to support the base of the bottle.

使用時，用手指封著一邊鼻孔，把噴嘴放進另一邊鼻孔，一邊輕輕地吸氣，一邊用食指和中指將白項圈按下，並用拇指托住瓶底。

4 Breathe out through your mouth and repeat for your second spray in the same nostril.

用嘴呼氣，然後在同一邊鼻孔再噴第二次。

5 Now repeat the whole process in the other nostril.

用同樣的方法噴另一邊鼻孔。

6 On completion replace dust cap.

用完後，蓋上防塵蓋。

Caution 注意事項

Beconase Aqueous Nasal Spray is not intended to give rapid relief of your nasal symptoms. It has been developed to control the underlying disorders responsible for your attacks so it is important that you should use it regularly at the times recommended by your doctor.

鼻可靈水性鼻用噴霧劑的藥效是用來控制促使病發的根源而不是作迅速緩解鼻部症狀之用，所以務必依照醫生指示定時使用。

7 Cleaning

To clean the nasal applicator, remove the dust cap, press gently **upwards** on the white collar and the nasal applicator will come free. Wash the applicator and dust cap under a cold tap. Dry and replace with the dust cap back in position.
If the nasal applicator becomes blocked, remove the dust cap, unscrew the complete pump mechanism and soak it in warm water for a few minutes. Rinse under a cold tap, dry and refit to bottle.

清洗

清洗噴霧器時，要先拿開防塵蓋，輕輕把白項圈**向上拉**，噴霧器便可拉開。用冷自來水清洗噴霧器和防塵蓋，弄乾後，就連同防塵蓋裝回瓶上。
如果噴霧器出現阻塞，拿開防塵蓋，把整個噴管結構扭開，放到溫水中浸幾分鐘，再用冷自來水清洗，弄乾後裝回瓶上。