Pages 1-4 inclusive exempt in full under section 22(1) of the FOI Act (irrelevant information)

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BECONASE ALLERGY 24 HOUR FLUTICASONE™ AQUEOUS NASAL SPRAY

Fluticasone propionate

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray.

This leaflet answers some common questions about BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Beconase ALLERGY 24 Hour Fluticasone Aqueous Nasal Spray is used for

BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray contains a steroid called fluticasone propionate, which treats inflamed tissue. The tiny amounts sprayed into your nose help to reduce swelling and irritation.

BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray is used to prevent and treat seasonal allergic rhinitis (eg. hayfever) and perennial rhinitis in adults and children aged 12 years and over.

When you have rhinitis, the inside of your nose becomes swollen and itchy. This usually occurs during spring and summer when it is caused by breathing pollens from grasses or trees. This condition is called hayfever. Some people get problems all the year round and this is called perennial rhinitis. It is often due to house dust mites or animals such as cats or dogs.

When you spray BECONASE ALLERGY 24 HOUR FLUTICASONE into your nose it helps to relieve the itching, sneezing and blocked or runny nose.

Ask your pharmacist or doctor if you have any questions or if you aren't sure why BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray has been recommended for you.

BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray is not addictive.

Before you use Beconase 24 Hour Fluticasone Aqueous Nasal Spray

When you must not use it

- **Do not use BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray if you have ever had an allergic reaction to fluticasone propionate, an allergic reaction to any other corticosteroid or any of the ingredients listed at the end of this leaflet.**

  Read the side effects section to find out the symptoms of an allergic reaction.

- **Do not use BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray after the expiry date (EXP) printed on the pack.**

  If you use it after the expiry date has passed, it may not work as well.

- **Do not use BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray, talk to your pharmacist or doctor.

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Before you start to use it

You must tell your Pharmacist or doctor if You:

- Are pregnant or planning to become pregnant
- Are breastfeeding
- Have recently had nasal ulcers, injury or surgery to your nose
- Have a tendency to nose bleeds
- Have a nasal or sinus infection
- Are under 12 years of age.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when using BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray with other medicines.

How to use Beconase ALLERGY 24 Hour Fluticasone Aqueous Nasal Spray

How much to use

If your BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray is new and you have not used it before, or if you have not used it for one week or more, you should activate six sprays into the air before use.

For adults and children aged 12 and over, the usual dose is two sprays into each nostril once daily, preferably in the morning.

When symptoms are under control a maintenance dose of one spray into each nostril once a day may be used. If symptoms reoccur the dosage may be increased to the original dose.

Do not use a larger dose or use your nasal spray more often than recommended in the instruction leaflet. Do not use more than 2 sprays in each nostril daily (4 sprays).

It may take a few days for this medicine to work and it is VERY IMPORTANT THAT YOU USE IT REGULARLY. If you stop the treatment when you feel better your symptoms may return as the medication wears off.

If your symptoms include itchy watery eyes and they trouble you, advise your doctor or pharmacist.

See your doctor or pharmacist if symptoms are not relieved within 7 days.

Using the spray

1. Shake the bottle and remove the dust cap.
2. Blow your nose gently.
3. Close one nostril as shown and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle.
4. Start to breathe in slowly through your nose. While you are breathing in squirt a spray of fine mist into your nostril by pressing down firmly on the collar with your fingers.
5. Breathe out through your mouth. Repeat step 4 to take a second spray in the same nostril.
6. Remove the nozzle from this nostril and breathe out through your mouth.
7. Repeat steps 3 to 6 for the other nostril.

AFTER USING THE SPRAY WIPE THE NOZZLE CAREFULLY WITH A CLEAN TISSUE OR HANDKERCHIEF, AND REPLACE THE DUST CAP.

How long to use the spray

Your pharmacist or doctor will tell you how long to use your BECONASE ALLERGY 24 HOUR FLUTICASONE for.

Do not use the spray for more than 6 months without the advice of your doctor or pharmacist.

If you forget to use the spray

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

If you use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much BECONASE ALLERGY 24 HOUR FLUTICASONE, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

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While you are using BECONASE ALLERGY 24 Hour Fluticasone Aqueous Nasal Spray

Things you must do

Tell your doctor or pharmacist that you are using Beconase ALLERGY 24 Hour Fluticasone Aqueous Nasal Spray if you are about to be started on any new medicines.

Tell your pharmacist or doctor if, for any reason, you have not used your medicine exactly as recommended.
Use **BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray** only in your nose.

Things you must not do

Do not give this medicine to anyone else, even if his or her symptoms seem similar to yours.

Do not use BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray to treat any other complaints unless advised by your doctor to do so.

Side-Effects

Check with your pharmacist or doctor as soon as possible if you have any problems while using BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

See your doctor or pharmacist if:

- Your nose bleeds;
- You develop signs or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharge;
- You have eye pain or visual disturbances.

Like other medicines, BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and may need medical attention.

The most commonly reported side-effects are:

- painful nose or throat
- nose bleed
- bad taste or smell

If any of these side effects persist, or are troublesome, see your doctor.

Stop using your spray and contact your doctor immediately if you develop any of the following:

- rash
- wheezing
- breathlessness
- Swelling of the lips/mouth

These could be symptoms of an allergic reaction

If you think you are having an allergic reaction to BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray, TELL YOUR DOCTOR IMMEDIATELY or go to the emergency department at your nearest hospital.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your pharmacist or doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Beconase 24 Hour Fluticasone Aqueous Nasal Spray

Storage

Keep this medicine where young children cannot reach it.

Keep BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray below 30°C.

Protect it from frost and light.

Do not refrigerate.

Do not store it, or any other medicine, in a bathroom or near a sink.

Heat and dampness can destroy some medicines.

Keep your BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray in its pack until it is time to take it.

If you take the product out of its packaging it may not keep well.

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Disposal

If your doctor tells you to stop using BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray, or the Product has passed its expiry date, ask your pharmacist what to do with any BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray left over.

Product description

What BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray looks like

BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray is contained in an amber glass bottle fitted with a metering pump, a nasal adaptor and a duct cover. Each bottle contains around 120 sprays.

Ingredients

BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray contains the active ingredient fluticasone propionate. It also contains the following inactive ingredients:

Dispersible cellulose, sodium carboxymethylcellulose, anhydrous glucose, polysorbate 80, hydrochloric acid (to adjust pH), purified water, benzalkonium chloride, phenethyl alcohol.

Sponsor

GlaxoSmithKline Consumer Healthcare

82 Hughes Avenue
Ermington, NSW 2115.

Further Information

This is not all the information that is available on BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.

Do not throw this leaflet away.
You may need to read it again.

This leaflet was prepared on 1 May 2002. The information provided applies only to: BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray.
™ BECONASE ALLERGY 24 HOUR FLUTICASONE is a trade mark of the Glaxo Wellcome Group of Companies.
BECONASE ALLERGY 24 HOUR FLUTICASONE Aqueous Nasal Spray: AUST R xxxxx

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PRODUCT INFORMATION

BECONASE ALLERGY 24 HOUR™ Fluticasone AQUEOUS NASAL SPRAY

AUSTRALIAN APPROVED NAME: Fluticasone propionate

PHYSICAL AND CHEMICAL CHARACTERISTICS:

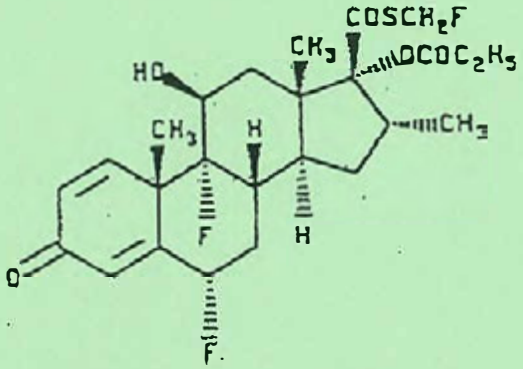
BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray (0.05% w/w) is an aqueous suspension of microfine fluticasone propionate for topical administration to the nasal mucosa by means of a metering, atomising spray pump. Each 100mg of spray delivered by the nasal adaptor contains 50µg of fluticasone propionate.

BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray also contains the following excipients: anhydrous glucose, cellulose - dispersible, phenethyl alcohol, benzalkonium chloride solution, polysorbate 80, hydrochloric acid, water - purified.

CHEMICAL NAME:

S-Fluoromethyl 6α, 9α-difluoro-11ß-hydroxy-16α-methyl-3-oxo-17 α-propionyloxy-androsta-1, 4-diene-17ß-carbothioate.

STRUCTURE:



CAS: 80474-14-2

MOLECULAR FORMULA: $C_{25}H_{31}F_3O_5S$

MODE OF ACTION:

Fluticasone propionate has potent anti-inflammatory activity but when used topically on the nasal mucosa has no detectable systemic activity.

Fluticasone propionate causes little or no hypothalamic-pituitary-adrenal axis suppression following intranasal administration. Following intranasal dosing of fluticasone propionate at the recommended dose (200mcg/day) no significant change in 24h serum cortisol AUC was found compared to placebo (ratio 1.01, 90%CI 0.9-1.14). After intranasal administration of high dose FP (2400mcg/day ie 12 times the recommended dose) a small change in 24h serum cortisol AUC was found compared to placebo (ratio 0.79, 90% CI 0.71-0.89).

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PHARMACOKINETICS:

The data for paediatric pharmacokinetics show consistency with the adult findings.

Absorption: Following intranasal dosing of fluticasone propionate, (200mcg/day) steady-state maximum plasma concentrations were not quantifiable in most subjects (<0.01ng/mL). The highest C_{max} observed was 0.017ng/mL. Following the recommended dose of 200mcg/day, the bioavailability could not be quantified in most subjects and the highest reported value was 1%. The amount of direct absorption in the nose is unknown but appears to be low due to the low aqueous solubility with the majority of the dose being eventually swallowed. When administered orally the systemic exposure is <1% due to poor absorption and pre-systemic metabolism. The absolute bioavailability of intranasal FP at high doses (2400mcg/day ie 12 times the recommended dose) is estimated as 1.26% (90% CI 0.85, 1.86).

Distribution: Fluticasone propionate has a large volume of distribution at steady-state (approximately 318L). Plasma protein binding is moderately high (91%).

Metabolism: Fluticasone propionate is cleared rapidly from the systemic circulation, principally by hepatic metabolism to an inactive carboxylic acid metabolite, by the cytochrome P450 enzyme CYP3A4. Swallowed fluticasone propionate is also subject to extensive first pass metabolism. Care should be taken when co-administering potent CYP3A4 inhibitors such as ketoconazole and ritonavir as there is potential for increased systemic exposure to fluticasone propionate.

Elimination: The elimination rate of intravenous administered fluticasone propionate is linear over the 250-1000mcg dose range and are characterized by a high plasma clearance (CL=1.1L/min). Peak plasma concentrations are reduced by approximately 98% within 3-4 hours and only low plasma concentrations were associated with the 7.8h terminal half-life. The renal clearance of fluticasone propionate is negligible (<0.2%) and less than 5% as the carboxylic acid metabolite. The major route of elimination is the excretion of fluticasone propionate and its metabolites in the bile.

CLINICAL TRIALS:

Rhinitis

Clinical Trials aimed to establish the efficacy of Fluticasone Propionate Aqueous Nasal Spray (FPANS) 200µg once daily (od) in adults with seasonal or perennial rhinitis. To determine that these dosages were optimal for treating adults and to compare the efficacy of FPANS 200µg od with that of the standard therapy, beclomethasone dipropionate aqueous nasal spray (BDPANS) 200µg was used twice daily (bd). Clinical trial data is available from over 4000 patients. Efficacy determination included daily symptom assessments.

Dose-ranging studies showed FPANS to be significantly superior to placebo in the relief of symptoms of rhinitis, even at very low doses (25µg twice daily), although higher doses (eg 200µg daily) provided significant improvements more rapidly.

Once daily doses of 200µg FPANS have been shown to be efficacious in patients with seasonal rhinitis. For the relief of adult perennial rhinitis, 200µg once daily was as effective as 100µg twice daily.

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Sinus pain & pressure
In patients with allergic rhinitis, fluticasone propionate aqueous nasal spray has also been shown to be of benefit for the management of associated sinus pain and pressure.

Two 14 days, randomised, double blind, parallel group clinical studies were performed in 401 adult and adolescent patients aged ≥12 years. Both studies compared BECONASE ALLERGY 24 HOUR fluticasone Nasal Spray 200 mcg once daily, administered as two 50mcg sprays per nostril, with placebo. The primary endpoint for both studies was the mean change from baseline in the patient-rated sinus pain and pressure score at week 2. In both studies, BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray provided significantly greater improvement compared with placebo for the primary endpoint ($p<0.05$). The magnitude of the improvement was 10 points compared to placebo and approximately 35 points from baseline (baseline score for this symptom was 75 on a 0-100 scale). The sinus pain and pressure score was also significantly decreased in the BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray treated group over the entire 2 week study period ($p<0.05$).

Treatment with BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray provided significantly greater improvement in symptoms of nasal congestion during week 1, 2 and overall during the 2 week study period ($p<0.05$). The overall improvement in congestion compared to placebo was 10 points and approximately 37 points from baseline (baseline score for this symptom was 78 on a 0-100 scale).

INDICATIONS:

Fluticasone Propionate Aqueous Nasal Spray is indicated for the short-term (3 – 6 months) prevention or treatment of seasonal allergic rhinitis and perennial rhinitis in adults and children over 12 years old.

CONTRAINDICATIONS:

Fluticasone Propionate Aqueous Nasal Spray is contra-indicated in patients with a hypersensitivity to any of its ingredients, or a history of allergic reaction to other corticosteroid medicines

PRECAUTIONS:

Local infection: Infections of the nasal airways should be appropriately treated but do not constitute a specific contra-indication to treatment with Fluticasone Propionate Aqueous Nasal Spray.

Although some beneficial effects of Fluticasone Propionate Aqueous Nasal Spray may be observed within 24 hours, the full benefit of Fluticasone Propionate Aqueous Nasal Spray may not be achieved until treatment has been administered for several days.

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

Although Fluticasone Propionate 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.

Rare instances of glaucoma and increased intra-ocular pressure have been reported following administration of intranasal corticosteroids, as a class effect.

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Candidiasis of the throat can occur in patients treated with intranasal steroids. Special care should be taken when treating patients who may be susceptible to candida infections (eg diabetics).

Because of the inhibitory effect of these drugs on wound healing, patients with recent nasal septal ulcers, nasal surgery or nasal trauma should not use intranasal corticosteroids until healing has occurred.

Adrenocortical function:
Intranasal steroid products are designed to deliver drug directly to the nasal mucosa in order to minimise overall systemic glucocorticoid exposure and side effects. However systemic effects such as HPA axis suppression, reduction of bone density and retardation of growth rate in children may occur with intranasal steroids, particularly at high doses prescribed for prolonged periods of time.

The lowest dose of BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray that causes suppression of the HPA axis or effects on bone mineral density or growth retardation has not yet been established. However, the systemic bioavailability of fluticasone propionate is low (estimated at 1.26% using high doses), when given as BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray, and this limits the potential for such systemic side effects. Measurement of serum cortisol and 24 hour urinary cortisol in the clinical studies in adults did not suggest any HPA axis suppression with recommended doses. Studies of effects on the HPA axis in children have not been conducted.

Carcinogenicity, Mutagenicity and Impairment of Fertility:
Fluticasone propionate has no mutagenic effect in vivo or in vitro, no tumorigenic potential in rodents and is non-irritant and non-sensitising in animal models.

No evidence of a tumorigenic effect was observed in either a 2 year study in rats receiving doses of fluticasone propionate up to 57 µg/kg/day by inhalation or in an 18 month study in mice receiving oral doses of fluticasone propionate up to 1 mg/kg/day. There was no evidence of a mutagenic potential in a standard battery of mutagenicity assays.

Use in Pregnancy: (Category B3)
There is insufficient evidence of safety of fluticasone propionate in human pregnancy. Systemically absorbed corticosteroids are known to induce fetotoxic and teratogenic effects in rodent studies. However, equivalent effects have not been reported when these compounds have been given to humans during pregnancy. Reproductive toxicity studies with fluticasone propionate in mice and rats have shown the expected fetotoxic and teratogenic effects at subcutaneous doses of 100 to 150 µg/kg/day and above. As with previous compounds of this class, these effects are unlikely to be relevant to human therapy. Direct intranasal application ensures minimal systemic exposure. As with other drugs, the use of BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

Use in Lactation:
The excretion of fluticasone propionate into human breast milk has not been investigated. Subcutaneous administration of tritiated drug to lactating rats resulted in measurable radioactivity in both plasma and milk (levels in milk were 3-7 times plasma levels) 1-8 hours post-dosing. However plasma levels in patients following intranasal application of fluticasone propionate at recommended doses are low, and the amount of fluticasone ingested by the newborn is estimated to be very small as a consequence of very low maternal plasma concentration.

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Effects on ability to drive and use machinery:

Fluticasone propionate is unlikely to affect the ability to drive or use machinery.

INTERACTIONS:

Care should be taken when co-administering known, strong CYP3A4 inhibitors, eg. Ritonavir and ketoconazole, as there is potential for increased systemic exposure to fluticasone propionate.

ADVERSE REACTIONS:

Adverse reactions in controlled clinical studies with BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray have been primarily associated with irritation of the nasal mucous membranes, and are consistent with those expected from application of a topical medication to an already inflamed membrane. The adverse reactions reported by patients treated with BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray were similar to those reported by patients receiving placebo.

The most frequently reported adverse reactions (≥1% in any treatment group) considered by the investigator to be potentially related to BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray or placebo in trials of seasonal allergic rhinitis are listed below. These studies conducted in 948 adults and in 499 children evaluated 14-28 days of treatment with recommended doses of BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray compared with placebo.

Adverse Reactions Reported Most Frequently in Clinical Trials of Seasonal Allergic Rhinitis

	Adults (age ≥ 12 years)			Children (age 4-11 years)		
	FANS 100 µg bd (n=312) %	FANS 200 µg od (n=322) %	Placebo (n=314) %	FANS 100 µg od (n=167) %	FANS 200 µg od (n=164) %	Placebo (n=168) %
Nasal burning	2.2	3.4	2.5	1.8	2.4	1.2
Pharyngitis	1.3	1.6	<1	<1	0	0
Runny nose	<1	1.6	<1	<1	<1	<1
Blood in nasal mucus	0	1.6	<1	0	<1	0
Epistaxis	1.6	2.8	2.2	3.0	3.7	3.6
Sneezing	<1	1.2	2.2	0	<1	0
Crusting in nostrils	0	0	0	1.2	0	0
Nasal congestion	0	0	0	0	1.2	0
Nasal ulcer	<1	0	0	1.2	1.2	1.2
Headache	1.3	2.5	1.9	1.2	1.2	1.2

FANS: BECONASE ALLERGY 24 HOUR Fluticasone Aqueous Nasal Spray

In two 6 month trials involving 831 patients aged 12-75 years with perennial allergic rhinitis, the adverse reactions reported by patients treated with BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray were similar in type and incidence to those reported in seasonal trials, with the exception of epistaxis (≤ 13.3%) and blood in nasal mucous (≤ 8.3%). In addition to the events reported most frequently in the seasonal trials, patients receiving BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray in the 6 month trials reported nasal soreness (≤ 2.5%), nasal excoriation (≤ 2.0%), sinusitis (≤ 1.6%), and nasal dryness (≤ 1.3%).

Infrequent adverse reactions (incidence of 0.1%-1% and greater than placebo) reported by patients receiving fluticasone propionate aqueous nasal spray at the recommended daily dose

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of 200 mcg (or 100 mcg per day for children 4-11 years of age) in the aforementioned clinical trials included pharyngeal irritation, nasal stinging, nausea and vomiting, unpleasant smell and taste, and sinus headache (0.3%); lacrimation, eye irritation, xerostomia, cough, urticaria, and rash (0.2%); and nasal septum perforation (0.1%).

In two clinical trials that investigated BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray in the management of the symptoms of sinus pain and pressure associated with allergic rhinitis, the adverse reactions considered by the investigator to be potentially drug related were similar in type to those reported in the seasonal trials. The more frequently reported drug related adverse reactions (≥1% in any treatment group) was epistaxis (2%), nasal burning (1%), blood in nasal mucus (1%) and sore throat (1%). The studies conducted in 401 patients aged 12-74 years and evaluated 14 days of treatment with recommended doses of BECONASE ALLERGY 24 HOUR Fluticasone Nasal Spray compared with placebo.

Post-Marketing Surveillance: In addition to adverse events reported from clinical trials, the following events have been identified during post-approval use of fluticasone propionate in clinical practice.

General: Hypersensitivity reactions including angioedema, skin rash, edema of the face or tongue, pruritis, wheezing, dyspnea, and rarely, bronchospasm and anaphylaxis/anaphylactic reactions have been reported.
Ear, Nose and Throat: Alteration or loss in sense of taste and/or smell, sore throat, throat irritation and dryness, hoarseness, and voice changes.
Eye: Dryness and irritation of the eyes, conjunctivitis, blurred vision, glaucoma, increased intraocular pressure, and cataracts.

DOSAGE AND ADMINISTRATION:

Fluticasone propionate is for administration by the intranasal route only. Although some beneficial effects may be seen within 24 hours, for full therapeutic benefit regular usage is essential. The absence of an immediate effect should be explained to the patient as maximum relief may not be obtained until after 3 to 4 days of treatment.

When symptoms are under control, a maintenance dose of one spray into each nostril once a day may be used. If symptoms reoccur the dosage may be increased accordingly. The minimum dose at which effective control of symptoms is maintained should be used.

Shake gently before use.

It is necessary to prime the pump before first use or after a period of non-use (1 week or more). After initial priming (six actuations), each actuation delivers 50mcg of Fluticasone Propionate in 100 mg of formulation through the nasal adapter

For the treatment of seasonal allergic rhinitis and perennial rhinitis in adults and children over 12 years old :

Two sprays into each nostril once a day, preferably in the morning.The maximum daily dose should not exceed 200 µg (4 sprays) per day.

Elderly:

The normal adult dosage is applicable.

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OVERDOSAGE:

There are no data available on the effects of acute or chronic overdosage with Fluticasone Propionate Aqueous Nasal Spray. Intra-nasal administration of 2400mcg fluticasonse per day (ie 12 times the recommended dose) for four days to healthy human volunteers caused a small degree of suppression of adrenal steroid production.

Suppression of adrenal steroid production may give rise to typical signs and symptoms of Cushing's disease, such as buffalo hump, puffiness of face, hypertension and elevated blood glucose. If such a condition were to occur, care should be taken to wean the patient slowly off the steroid due to the probability of adrenal impairment. Recovery from impaired adrenocortical function caused by prolonged steroid therapy is usually slow and has been know to last up to 12 months.

PRESENTATION:

Fluticasone Propionate Aqueous Nasal Spray is supplied in an amber glass bottle fitted with a metering, atomising pump, nasal adaptor and a dust cover. Bottles of approximately 60 or approximately 120 metered sprays, when used as recommended.

Fluticasone Propionate Aqueous Nasal Spray contains the antimicrobial preservatives benzalkonium chloride (BKC) and phenethyl alcohol. The effects of BKC on nasal mucosa and ciliary function have been examined, and no damaging effects have been observed in clinical studies of up to 1 year duration.

STORAGE CONDITIONS:

Fluticasone Propionate Aqueous Nasal Spray should be stored below 30 degrees celsius. Protect from light. Do not refrigerate

POISON SCHEDULE: S3 (PHARMACIST ONLY MEDICINE)

SPONSOR:

GlaxoSmithKline Consumer
Healthcare
82 Hughes Avenue
Ermington NSW 2115.

DATE OF TGA APPROVAL:

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