

1 **PRESCRIBING INFORMATION**

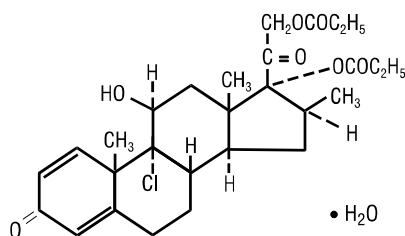
2 **BECONASE AQ<sup>®</sup>**  
3 **(beclomethasone dipropionate,**  
4 **monohydrate)**  
5 **Nasal Spray, 42 mcg**

6  
7 **For Intranasal Use Only.**

**SHAKE WELL  
BEFORE USE.**

8 **DESCRIPTION**

9 Beclomethasone dipropionate, monohydrate, the active component of BECONASE AQ Nasal  
10 Spray, is an anti-inflammatory steroid having the chemical name 9-chloro-11 $\beta$ ,17,21-trihydroxy-  
11 16 $\beta$ -methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, monohydrate and the following  
12 chemical structure:



14  
15  
16 Beclomethasone 17,21-dipropionate is a diester of beclomethasone, a synthetic halogenated  
17 corticosteroid. Beclomethasone dipropionate, monohydrate is a white to creamy-white, odorless  
18 powder with a molecular weight of 539.06. It is very slightly soluble in water, very soluble in  
19 chloroform, and freely soluble in acetone and in ethanol.

20 BECONASE AQ Nasal Spray is a metered-dose, manual pump spray unit containing a  
21 microcrystalline suspension of beclomethasone dipropionate, monohydrate equivalent to 42 mcg  
22 of beclomethasone dipropionate, calculated on the dried basis, in an aqueous medium containing  
23 microcrystalline cellulose, carboxymethylcellulose sodium, dextrose, benzalkonium chloride,  
24 polysorbate 80, and 0.25% v/w phenylethyl alcohol. The pH through expiry is 5.0 to 6.8.

25 After initial priming (6 actuations), each actuation of the pump delivers from the nasal adapter  
26 100 mg of suspension containing beclomethasone dipropionate, monohydrate equivalent to  
27 42 mcg of beclomethasone dipropionate. If the pump is not used for 7 days, it should be primed  
28 until a fine spray appears. Each 25-g bottle of BECONASE AQ Nasal Spray provides 180  
29 metered sprays.

30 **CLINICAL PHARMACOLOGY**

31 **Mechanism of Action:** Following topical administration, beclomethasone dipropionate  
32 produces anti-inflammatory and vasoconstrictor effects. The mechanisms responsible for the  
33 anti-inflammatory action of beclomethasone dipropionate are unknown. Corticosteroids have  
34 been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils,

35 neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids,  
36 leukotrienes, and cytokines) involved in inflammation. The direct relationship of these findings  
37 to the effects of beclomethasone dipropionate on allergic rhinitis symptoms is not known.

38 Biopsies of nasal mucosa obtained during clinical studies showed no histopathologic changes  
39 when beclomethasone dipropionate was administered intranasally.

40 Beclomethasone dipropionate is a pro-drug with weak glucocorticoid receptor binding  
41 affinity. It is hydrolyzed via esterase enzymes to its active metabolite beclomethasone-17-  
42 monopropionate (B-17-MP), which has high topical anti-inflammatory activity.

43 **Pharmacokinetics: Absorption:** Beclomethasone dipropionate is sparingly soluble in water.  
44 When given by nasal inhalation in the form of an aqueous or aerosolized suspension, the drug is  
45 deposited primarily in the nasal passages. The majority of the drug is eventually swallowed.  
46 Following intranasal administration of aqueous beclomethasone dipropionate, the systemic  
47 absorption was assessed by measuring the plasma concentrations of its active metabolite  
48 B-17-MP, for which the absolute bioavailability following intranasal administration is 44% (43%  
49 of the administered dose came from the swallowed portion and only 1% of the total dose was  
50 bioavailable from the nose). The absorption of unchanged beclomethasone dipropionate  
51 following oral and intranasal dosing was undetectable (plasma concentrations <50 pg/mL).

52 **Distribution:** The tissue distribution at steady state for beclomethasone dipropionate is  
53 moderate (20 L) but more extensive for B-17-MP (424 L). There is no evidence of tissue storage  
54 of beclomethasone dipropionate or its metabolites. Plasma protein binding is moderately high  
55 (87%).

56 **Metabolism:** Beclomethasone dipropionate is cleared very rapidly from the systemic  
57 circulation by metabolism mediated via esterase enzymes that are found in most tissues. The  
58 main product of metabolism is the active metabolite (B-17-MP). Minor inactive metabolites,  
59 beclomethasone-21-monopropionate (B-21-MP) and beclomethasone (BOH), are also formed,  
60 but these contribute little to systemic exposure.

61 **Elimination:** The elimination of beclomethasone dipropionate and B-17-MP after  
62 intravenous administration are characterized by high plasma clearance (150 and 120 L/hour)  
63 with corresponding terminal elimination half-lives of 0.5 and 2.7 hours. Following oral  
64 administration of tritiated beclomethasone dipropionate, approximately 60% of the dose was  
65 excreted in the feces within 96 hours, mainly as free and conjugated polar metabolites.  
66 Approximately 12% of the dose was excreted as free and conjugated polar metabolites in the  
67 urine. The renal clearance of beclomethasone dipropionate and its metabolites is negligible.

68 **Pharmacodynamics:** The effects of beclomethasone dipropionate on  
69 hypothalamic-pituitary-adrenal (HPA) function have been evaluated in adult volunteers by other  
70 routes of administration. Studies with beclomethasone dipropionate by the intranasal route may  
71 demonstrate that there is more or that there is less absorption by this route of administration.  
72 There was no suppression of early morning plasma cortisol concentrations when beclomethasone  
73 dipropionate was administered in a dose of 1,000 mcg/day for 1 month as an oral aerosol or for  
74 3 days by intramuscular injection. However, partial suppression of plasma cortisol concentrations

75 was observed when beclomethasone dipropionate was administered in doses of 2,000 mcg/day  
76 either by oral aerosol or intramuscular injection. Immediate suppression of plasma cortisol  
77 concentrations was observed after single doses of 4,000 mcg of beclomethasone dipropionate.  
78 Suppression of HPA function (reduction of early morning plasma cortisol levels) has been  
79 reported in adult patients who received 1,600-mcg daily doses of oral beclomethasone  
80 dipropionate for 1 month. In clinical studies using beclomethasone dipropionate aerosol  
81 intranasally, there was no evidence of adrenal insufficiency. The effect of BECONASE AQ  
82 Nasal Spray on HPA function was not evaluated but would not be expected to differ from  
83 intranasal beclomethasone dipropionate aerosol.

84 In 1 study in children with asthma, the administration of inhaled beclomethasone at  
85 recommended daily doses for at least 1 year was associated with a reduction in nocturnal cortisol  
86 secretion. The clinical significance of this finding is not clear. It reinforces other evidence,  
87 however, that topical beclomethasone may be absorbed in amounts that can have systemic effects  
88 and that physicians should be alert for evidence of systemic effects, especially in chronically  
89 treated patients (see PRECAUTIONS).

## 90 **INDICATIONS AND USAGE**

91 BECONASE AQ Nasal Spray is indicated for the relief of the symptoms of seasonal or  
92 perennial allergic and nonallergic (vasomotor) rhinitis.

93 Results from 2 clinical trials have shown that significant symptomatic relief was obtained  
94 within 3 days. However, symptomatic relief may not occur in some patients for as long as  
95 2 weeks. BECONASE AQ Nasal Spray should not be continued beyond 3 weeks in the absence  
96 of significant symptomatic improvement. BECONASE AQ Nasal Spray should not be used in the  
97 presence of untreated localized infection involving the nasal mucosa.

98 BECONASE AQ Nasal Spray is also indicated for the prevention of recurrence of nasal  
99 polyps following surgical removal.

100 Clinical studies have shown that treatment of the symptoms associated with nasal polyps may  
101 have to be continued for several weeks or more before a therapeutic result can be fully assessed.  
102 Recurrence of symptoms due to polyps can occur after stopping treatment, depending on the  
103 severity of the disease.

## 104 **CONTRAINDICATIONS**

105 Hypersensitivity to any of the ingredients of this preparation contraindicates its use.

## 106 **WARNINGS**

107 The replacement of a systemic corticosteroid with BECONASE AQ Nasal Spray can be  
108 accompanied by signs of adrenal insufficiency.

109 Careful attention must be given when patients previously treated for prolonged periods with  
110 systemic corticosteroids are transferred to BECONASE AQ Nasal Spray. This is particularly  
111 important in those patients who have associated asthma or other clinical conditions where too  
112 rapid a decrease in systemic corticosteroids may cause a severe exacerbation of their symptoms.

113 If recommended doses of intranasal beclomethasone are exceeded or if individuals are  
114 particularly sensitive or predisposed by virtue of recent systemic steroid therapy, symptoms of  
115 hypercorticism may occur, including very rare cases of menstrual irregularities, acneiform  
116 lesions, cataracts, and cushingoid features. If such changes occur, BECONASE AQ Nasal Spray  
117 should be discontinued slowly consistent with accepted procedures for discontinuing oral steroid  
118 therapy.

119 Persons who are using drugs that suppress the immune system are more susceptible to  
120 infections than healthy individuals. Chickenpox and measles, for example, can have a more  
121 serious or even fatal course in susceptible children or adults using corticosteroids. In children or  
122 adults who have not had these diseases or been properly immunized, particular care should be  
123 taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect  
124 the risk of developing a disseminated infection is not known. The contribution of the underlying  
125 disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to  
126 chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If  
127 exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be  
128 indicated. (See the respective package inserts for complete VZIG and IG prescribing  
129 information.) If chickenpox develops, treatment with antiviral agents may be considered.

130 Avoid spraying in eyes.

## 131 **PRECAUTIONS**

132 **General:** Intranasal corticosteroids may cause a reduction in growth velocity when administered  
133 to pediatric patients (see PRECAUTIONS: Pediatric Use).

134 During withdrawal from oral corticosteroids, some patients may experience symptoms of  
135 withdrawal, e.g., joint and/or muscular pain, lassitude, and depression.

136 Rarely, immediate hypersensitivity reactions may occur after the intranasal administration of  
137 beclomethasone (see ADVERSE REACTIONS).

138 Rare instances of nasal septum perforation have been spontaneously reported.

139 Rare instances of wheezing, cataracts, glaucoma, and increased intraocular pressure have been  
140 reported following the intranasal use of beclomethasone dipropionate.

141 In clinical studies with beclomethasone dipropionate administered intranasally, the  
142 development of localized infections of the nose and pharynx with *Candida albicans* has occurred  
143 only rarely. When such an infection develops, it may require treatment with appropriate local  
144 therapy and discontinuation of treatment with BECONASE AQ Nasal Spray.

145 If persistent nasopharyngeal irritation occurs, it may be an indication for stopping  
146 BECONASE AQ Nasal Spray.

147 Beclomethasone dipropionate is absorbed into the circulation. Use of excessive doses of  
148 BECONASE AQ Nasal Spray may suppress HPA function.

149 Intranasal corticosteroids should be used with caution, if at all, in patients with active or  
150 quiescent tuberculous infections of the respiratory tract, untreated local or systemic fungal or  
151 bacterial infections, systemic viral or parasitic infections, or ocular herpes simplex.

152 For BECONASE AQ Nasal Spray to be effective in the treatment of nasal polyps, the spray  
153 must be able to enter the nose. Therefore, treatment of nasal polyps with BECONASE AQ Nasal  
154 Spray should be considered adjunctive therapy to surgical removal and/or the use of other  
155 medications that will permit effective penetration of BECONASE AQ Nasal Spray into the nose.  
156 Nasal polyps may recur after any form of treatment.

157 As with any long-term treatment, patients using BECONASE AQ Nasal Spray over several  
158 months or longer should be examined periodically for possible changes in the nasal mucosa.

159 Because of the inhibitory effect of corticosteroids on wound healing, patients who have  
160 experienced recent nasal septal ulcers, nasal surgery, or nasal trauma should not use a nasal  
161 corticosteroid until healing has occurred.

162 Although systemic effects have been minimal with recommended doses, this potential  
163 increases with excessive doses. Therefore, larger than recommended doses should be avoided.

164 **Information for Patients:** Patients being treated with BECONASE AQ Nasal Spray should  
165 receive the following information and instructions. This information is intended to aid them in  
166 the safe and effective use of this medication. It is not a disclosure of all possible adverse or  
167 intended effects.

168 Patients should use BECONASE AQ Nasal Spray at regular intervals since its effectiveness  
169 depends on its regular use. The patient should take the medication as directed. It is not acutely  
170 effective, and the prescribed dosage should not be increased. Instead, nasal vasoconstrictors or  
171 oral antihistamines may be needed until the effects of BECONASE AQ Nasal Spray are fully  
172 manifested. One to 2 weeks may pass before full relief is obtained. The patient should contact the  
173 physician if symptoms do not improve, if the condition worsens, or if sneezing or nasal irritation  
174 occurs.

175 For the proper use of BECONASE AQ Nasal Spray and to attain maximum improvement, the  
176 patient should read and follow carefully the patient's instructions accompanying the product.

177 Persons who are using immunosuppressant doses of corticosteroids should be warned to avoid  
178 exposure to chickenpox or measles. Patients should also be advised that if they are exposed,  
179 medical advice should be sought without delay.

180 **Carcinogenesis, Mutagenesis, Impairment of Fertility:** The carcinogenicity of  
181 beclomethasone dipropionate was evaluated in rats that were exposed for a total of 95 weeks,  
182 13 weeks at inhalation doses up to 0.4 mg/kg and the remaining 82 weeks at combined oral and  
183 inhalation doses up to 2.4 mg/kg. There was no evidence of carcinogenicity in this study at the  
184 highest dose, approximately 60 times the maximum recommended daily intranasal dose in adults  
185 on a mg/m<sup>2</sup> basis or approximately 35 times the maximum recommended daily intranasal dose in  
186 children on a mg/m<sup>2</sup> basis.

187 Beclomethasone dipropionate did not induce gene mutation in bacterial cells or mammalian  
188 Chinese hamster ovary (CHO) cells in vitro. No significant clastogenic effect was seen in  
189 cultured CHO cells in vitro or in the mouse micronucleus test in vivo.

190 In rats, beclomethasone dipropionate caused decreased conception rates at an oral dose of  
191 16 mg/kg (approximately 390 times the maximum recommended daily intranasal dose in adults

192 on a mg/m<sup>2</sup> basis). There was no significant effect of beclomethasone dipropionate on fertility in  
193 rats at oral doses of 1.6 mg/kg (approximately 40 times the maximum recommended daily  
194 intranasal dose in adults on a mg/m<sup>2</sup> basis). Inhibition of the estrous cycle in dogs was observed  
195 following oral dosing at 0.5 mg/kg (approximately 40 times the maximum recommended daily  
196 intranasal dose in adults on a mg/m<sup>2</sup> basis). No inhibition of the estrous cycle in dogs was seen  
197 following 12 months' exposure at an estimated inhalation dose of 0.33 mg/kg (approximately 25  
198 times the maximum recommended daily intranasal dose in adults on a mg/m<sup>2</sup> basis).

199 **Pregnancy: Teratogenic Effects:** Pregnancy Category C. Like other corticosteroids,  
200 beclomethasone dipropionate was teratogenic and embryocidal in the mouse and rabbit at a  
201 subcutaneous dose of 0.1 mg/kg in mice or 0.025 mg/kg in rabbits (approximately equal to the  
202 maximum recommended daily intranasal dose in adults on a mg/m<sup>2</sup> basis). No teratogenicity or  
203 embryocidal effects were seen in rats when exposed to an inhalation dose of 0.1 mg/kg plus oral  
204 doses of up to 10 mg/kg per day for a combined dose of 10.1 mg/kg (approximately 240 times the  
205 maximum recommended daily intranasal dose in adults on a mg/m<sup>2</sup> basis).

206 There are no adequate and well-controlled studies in pregnant women. Beclomethasone  
207 dipropionate should be used during pregnancy only if the potential benefit justifies the potential  
208 risk to the fetus.

209 **Nonteratogenic Effects:** Hypoadrenalism may occur in infants born of mothers receiving  
210 corticosteroids during pregnancy. Such infants should be carefully observed.

211 **Nursing Mothers:** It is not known whether beclomethasone dipropionate is excreted in human  
212 milk. Because other corticosteroids are excreted in human milk, caution should be exercised  
213 when BECONASE AQ Nasal Spray is administered to a nursing woman.

214 **Pediatric Use:** The safety and effectiveness of BECONASE AQ Nasal Spray have been  
215 established in children aged 6 years and above through evidence from extensive clinical use in  
216 adult and pediatric patients. The safety and effectiveness of BECONASE AQ Nasal Spray in  
217 children below 6 years of age have not been established.

218 Controlled clinical studies have shown that intranasal corticosteroids may cause a reduction in  
219 growth velocity in pediatric patients. This effect has been observed in the absence of laboratory  
220 evidence of HPA axis suppression, suggesting that growth velocity is a more sensitive indicator  
221 of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA  
222 axis function. The long-term effects of this reduction in growth velocity associated with  
223 intranasal corticosteroids, including the impact on final adult height, are unknown. The potential  
224 for "catch-up" growth following discontinuation of treatment with intranasal corticosteroids has  
225 not been adequately studied. The growth of pediatric patients receiving intranasal corticosteroids,  
226 including BECONASE AQ Nasal Spray, should be monitored routinely (e.g., via stadiometry).  
227 The potential growth effects of prolonged treatment should be weighed against the clinical  
228 benefits obtained and the risks/benefits of treatment alternatives. To minimize the systemic  
229 effects of intranasal corticosteroids, including BECONASE AQ Nasal Spray, each patient should  
230 be titrated to the lowest dose that effectively controls his/her symptoms.

231 In a double-blind, controlled trial, 100 children between the ages of 6 and 9½ years with  
232 allergic rhinitis were randomized to receive aqueous intranasal beclomethasone dipropionate  
233 168 mcg twice daily or placebo for 1 year. As measured by stadiometry, children who received  
234 beclomethasone dipropionate grew more slowly than those who received placebo. A difference in  
235 mean change in height was observed within 1 month of drug initiation. At the end of 12 months,  
236 the beclomethasone dipropionate-treated group had a growth velocity on average of 4.75 cm/year  
237 compared to 6.20 cm/year in the placebo group (p<0.01). While the placebo group had an  
238 expected distribution of growth velocity, approximately 50% of the beclomethasone  
239 dipropionate-treated children grew below the 10<sup>th</sup> percentile.

240 In children 7.3 years of age, the mean age of children in this study, the range for expected  
241 growth velocity is: boys – 3<sup>rd</sup> percentile = 4.1 cm/year, 50<sup>th</sup> percentile = 5.8 cm/year, and 97<sup>th</sup>  
242 percentile = 7.5 cm/year; girls – 3<sup>rd</sup> percentile = 4.3 cm/year, 50<sup>th</sup> percentile = 5.9 cm/year, and  
243 97<sup>th</sup> percentile = 7.5 cm/year. The potential reversibility of the reduction in growth velocity was  
244 not studied. No significant differences were observed between the 2 groups for mean basal  
245 plasma cortisol or ACTH-stimulated plasma cortisol levels.

246 **Geriatric Use:** Clinical studies of BECONASE AQ Nasal Spray did not include sufficient  
247 numbers of subjects aged 65 and over to determine whether they respond differently from  
248 younger subjects. Other reported clinical experience has not identified differences in responses  
249 between the elderly and younger patients. In general, dose selection for an elderly patient should  
250 be cautious, starting at the low end of the dosing range, reflecting the greater frequency of  
251 decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

## 252 **ADVERSE REACTIONS**

253 In general, side effects in clinical studies have been primarily associated with irritation of the  
254 nasal mucous membranes.

255 Adverse reactions reported in controlled clinical trials and open studies in patients treated with  
256 BECONASE AQ Nasal Spray are described below.

257 Mild nasopharyngeal irritation following the use of beclomethasone aqueous nasal spray has  
258 been reported in up to 24% of patients treated, including occasional sneezing attacks (about 4%)  
259 occurring immediately following use of the spray. In patients experiencing these symptoms, none  
260 had to discontinue treatment. The incidence of transient irritation and sneezing was  
261 approximately the same in the group of patients who received placebo in these studies, implying  
262 that these complaints may be related to vehicle components of the formulation.

263 Fewer than 5 per 100 patients reported headache, nausea, or lightheadedness following the use  
264 of BECONASE AQ Nasal Spray. Fewer than 3 per 100 patients reported nasal stuffiness,  
265 nosebleeds, rhinorrhea, or tearing eyes.

266 Rare cases of ulceration of the nasal mucosa and instances of nasal septum perforation have  
267 been spontaneously reported (see PRECAUTIONS).

268 Reports of dryness and irritation of the nose and throat and unpleasant taste and smell have  
269 been received. There are rare reports of loss of taste and smell.

270 Rare instances of wheezing, cataracts, glaucoma, and increased intraocular pressure have been  
271 reported following the use of intranasal beclomethasone dipropionate (see PRECAUTIONS).

272 Rare cases of immediate and delayed hypersensitivity reactions, including  
273 anaphylactoid/anaphylactic reactions, urticaria, angioedema, rash, and bronchospasm, have been  
274 reported following the oral and intranasal inhalation of beclomethasone dipropionate.

275 Cases of growth suppression have been reported for intranasal corticosteroids, including  
276 BECONASE AQ (see PRECAUTIONS: Pediatric Use).

## 277 **OVERDOSAGE**

278 When used at excessive doses, systemic corticosteroid effects such as hypercorticism and  
279 adrenal suppression may appear. If such changes occur, BECONASE AQ Nasal Spray should be  
280 discontinued slowly consistent with accepted procedures for discontinuing oral steroid therapy.  
281 No deaths occurred when beclomethasone dipropionate was given as single oral doses of  
282 3,000 mg/kg to mice (approximately 36,000 times the maximum recommended daily intranasal  
283 dose in adults on a mg/m<sup>2</sup> basis, or approximately 21,000 times the maximum recommended  
284 daily intranasal dose in children on a mg/m<sup>2</sup> basis) and 2,000 mg/kg to rats (approximately  
285 48,000 times the maximum recommended daily intranasal dose in adults or approximately 29,000  
286 times the maximum recommended daily intranasal dose in children on a mg/m<sup>2</sup> basis). One bottle  
287 of BECONASE AQ Nasal Spray contains beclomethasone dipropionate, monohydrate equivalent  
288 to 10.5 mg of beclomethasone dipropionate; therefore, acute overdosage is unlikely.

## 289 **DOSAGE AND ADMINISTRATION**

290 **Adults and Children 12 Years of Age and Older:** The usual dosage is 1 or 2 nasal  
291 inhalations (42 to 84 mcg) in each nostril twice a day (total dose, 168 to 336 mcg/day).

292 **Children 6 to 12 Years of Age:** Patients should be started with 1 nasal inhalation in each  
293 nostril twice daily; patients not adequately responding to 168 mcg or those with more severe  
294 symptoms may use 336 mcg (2 inhalations in each nostril). Once adequate control is achieved,  
295 the dosage should be decreased to 84 mcg (1 spray in each nostril) twice daily. BECONASE AQ  
296 Nasal Spray is *not* recommended for children below 6 years of age.

297 The maximum total daily dosage should not exceed 2 sprays in each nostril twice daily  
298 (336 mcg/day).

299 In patients who respond to BECONASE AQ Nasal Spray, an improvement of the symptoms of  
300 seasonal or perennial rhinitis usually becomes apparent within a few days after the start of  
301 therapy with BECONASE AQ Nasal Spray. However, symptomatic relief may not occur in some  
302 patients for as long as 2 weeks. BECONASE AQ Nasal Spray should not be continued beyond  
303 3 weeks in the absence of significant symptomatic improvement.

304 The therapeutic effects of corticosteroids, unlike those of decongestants, are not immediate.  
305 This should be explained to the patient in advance in order to ensure cooperation and  
306 continuation of treatment with the prescribed dosage regimen.



307 In the presence of excessive nasal mucous secretion or edema of the nasal mucosa, the drug  
308 may fail to reach the site of intended action. In such cases it is advisable to use a nasal  
309 vasoconstrictor during the first 2 to 3 days of therapy with BECONASE AQ Nasal Spray.  
310 **Directions for Use:** Illustrated Patient's Instructions for Use accompany each package of  
311 BECONASE AQ Nasal Spray.

312 **HOW SUPPLIED**

313 BECONASE AQ Nasal Spray, 42 mcg is supplied in an amber glass bottle fitted with a  
314 metering atomizing pump and nasal adapter in a box of 1 (NDC 0173-0388-79) with patient's  
315 instructions for use. Each bottle contains 25 g of suspension and will provide 180 metered sprays.  
316 The correct amount of medication in each spray cannot be assured after 180 sprays even though  
317 the bottle is not completely empty. The bottle should be discarded when the labeled number of  
318 actuations has been used.

319 **Store between 15° and 30°C (59° and 86°F).**  
320  
321



322 GlaxoSmithKline  
323 GlaxoSmithKline  
324 Research Triangle Park, NC 27709  
325

326 April 2005 RL-2182  
327

---

**PHARMACIST—DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT**

---

328

329

330

331

332

333

334

335

336

337

338

339

340

341

342

**BECONASE AQ<sup>®</sup>**  
**(beclomethasone dipropionate,**  
**monohydrate)**  
**Nasal Spray, 42 mcg**

**For Intranasal Use Only.**

**SHAKE WELL BEFORE USE.**

**Patient's Instructions for Use**

**Shake the suspension spray bottle well before using it. Read complete instructions carefully and use only as directed.**

**To Use:**

343 1. Remove the safety clip and the plastic dust cap from the nasal applicator (Figure 1).

344

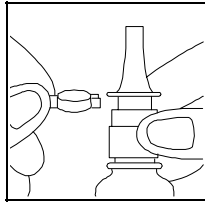


Figure 1

345

346

347

348 2. The very first time the spray is used, prime the pump into the air by pressing downward on the  
349 white collar, using your forefinger and middle finger while supporting the base of the bottle with  
350 your thumb. When you prime the pump for the first time, press down and release the pump 6  
351 times or until a fine spray appears (Figure 2).

352

353 The pump is now ready for use. If the pump is not used for 7 days, prime until a fine spray  
354 appears.

355

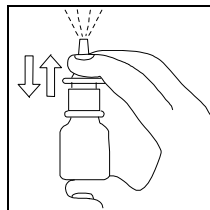


Figure 2

356

357

358

359 3. Gently blow your nose to clear your nostrils. Close 1 nostril. Tilt your head forward slightly  
360 and, keeping the bottle upright, carefully insert the nasal applicator into the other nostril (Figure  
361 3).

362

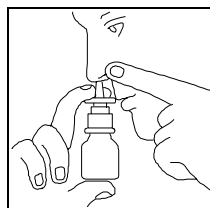


Figure 3

363

364

365

366 4. For each spray, press firmly downward once on the white collar, using your forefinger and  
367 middle finger while supporting the base of the bottle with your thumb. Avoid spraying in eyes.  
368 Breathe gently inward through the nostril.

369

370 5. Breathe out through your mouth.

371

372 6. Repeat steps 5 through 7 in the other nostril.

373

374 7. Replace the plastic dust cap and safety clip.

375

376 **8. DISCARD THE BOTTLE AFTER** the date calculated by your doctor or pharmacist. The  
377 correct amount of medication in each spray cannot be assured after 180 sprays even though the  
378 bottle is not completely empty. Discard the bottle after 180 sprays. Before the discard date you  
379 should consult your doctor to see if a refill is needed. Do not take extra doses or stop taking  
380 BECONASE AQ Nasal Spray without consulting your doctor.

381

382 **Cleansing:** To clean the nasal applicator, remove the plastic dust cap and safety clip and then  
383 press gently upward on the white collar to free the nasal applicator. Wash the applicator and  
384 dust cap with cold water. Dry and replace with the plastic dust cap and safety clip back in  
385 position.

386 If the nasal applicator becomes blocked, remove the dust cap, unscrew the complete pump  
387 mechanism, and soak the pump in warm water for a few minutes. Rinse with cold water, dry,  
388 refit to bottle, and reprime the pump.

389

390 **Caution:** BECONASE AQ Nasal Spray is not intended to give rapid relief of your nasal  
391 symptoms. BECONASE AQ Nasal Spray controls the underlying disorders responsible for  
392 your attacks, so it is important that you use it regularly at the times recommended by your  
393 doctor. The full benefit of BECONASE AQ Nasal Spray may take a few days to develop.

394

395 **Storage:** Store between 15° and 30°C (59° and 86°F).

396

397



398

399 GlaxoSmithKline

400 Research Triangle Park, NC 27709

401

402 April 2005

RL-2182