

1 PRESCRIBING INFORMATION

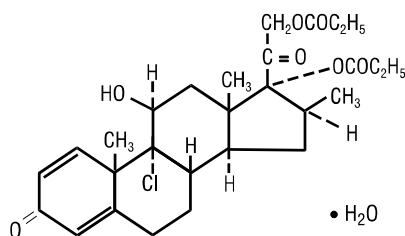
2 **BECONASE AQ[®]**
3 **(beclomethasone dipropionate,**
4 **monohydrate)**
5 **Nasal Spray, 42 mcg**

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 β ,17,21-trihydroxy-
11 16 β -methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, monohydrate and the following
12 chemical structure:
13



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/m² basis or approximately 35 times the maximum recommended daily intranasal dose in
186 children on a mg/m² 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/m² 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/m² 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/m² 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/m² 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/m² 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/m² 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 10th 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 – 3rd percentile = 4.1 cm/year, 50th percentile = 5.8 cm/year, and 97th
242 percentile = 7.5 cm/year; girls – 3rd percentile = 4.3 cm/year, 50th percentile = 5.9 cm/year, and
243 97th 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/m² basis, or approximately 21,000 times the maximum recommended
284 daily intranasal dose in children on a mg/m² 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/m² 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



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324 Research Triangle Park, NC 27709
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326 April 2005 RL-2182
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PHARMACIST—DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

328
329
330 **BECONASE AQ[®]**
331 **(beclomethasone dipropionate,**
332 **monohydrate)**
333 **Nasal Spray, 42 mcg**
334

335 **For Intranasal Use Only.**

SHAKE WELL BEFORE USE.

336
337 **Patient's Instructions for Use**
338

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

341
342 **To Use:**

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

344

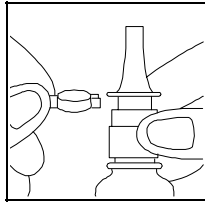


Figure 1

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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

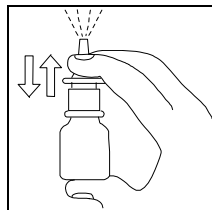


Figure 2

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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).

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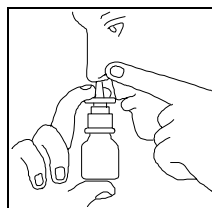


Figure 3

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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).

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