

1 **MEDICATION GUIDE**

2

3 **SYMBICORT 80/4.5**

4 *(budesonide 80 mcg and formoterol fumarate*
5 *dihydrate 4.5 mcg) Inhalation Aerosol*

6

7 **SYMBICORT 160/4.5**

8 *(budesonide 160 mcg and formoterol fumarate*
9 *dihydrate 4.5 mcg) Inhalation Aerosol*

10

11 Read the Medication Guide that comes with
12 SYMBICORT before you start using it and each time
13 you get a refill. There may be new information. This
14 Medication Guide does not take the place of talking to
15 your healthcare provider about your medical condition
16 or treatment.

17

18 **What is the most important information I should**
19 **know about SYMBICORT?**

- 20
- 21 • SYMBICORT contains 2 medicines:
 - 22 ○ Budesonide (the same medicine found in
 - 23 PULMICORT TURBUHALER[®]) an inhaled
 - 24 corticosteroid medicine. Inhaled
 - 25 corticosteroids help to decrease inflammation
 - 26 in the lungs. Inflammation in the lungs can
 - 27 lead to asthma symptoms.
 - 28 ○ Formoterol (the same medicine found in
 - 29 FORADIL[®] AEROLIZER[®]), a long-acting
 - 30 beta₂-agonist medicine or LABA. LABA
 - 31 medicines are used in patients with asthma.
 - 32 LABA medicines help the muscles around
 - 33 the airways in your lungs stay relaxed to
 - 34 prevent asthma symptoms, such as wheezing
 - 35 and shortness of breath. These symptoms can
 - 36 happen when the muscles around the airways
 - 37 tighten. This makes it hard to breathe. In
 - 38 severe cases, wheezing can stop your
 - 39 breathing and may lead to death if not treated
 - 40 right away.
 - 41
 - 42 • **In patients with asthma, LABA medicines such as**
 - 43 **formoterol (one of the medicines in**
 - 44 **SYMBICORT) may increase the chance of death**

45 **from asthma problems.** In a large asthma study,
46 more patients who used another LABA medicine,
47 died from asthma problems compared with patients
48 who did not use that LABA medicine. Talk with
49 your healthcare provider about this risk and the
50 benefits of treating your asthma with SYMBICORT.

51

52 • **SYMBICORT does not relieve sudden symptoms.**
53 **Always have an inhaled short-acting beta₂-**
54 **agonist medicine with you to treat sudden**
55 **symptoms. If you do not have this type of**
56 **medicine, contact your healthcare provider to**
57 **have one prescribed for you.**

58

59 • **Do not stop using SYMBICORT unless told to do**
60 **so by your healthcare provider because your**
61 **symptoms might get worse.**

62

63 • **SYMBICORT should be used only if your**
64 **healthcare provider decides that another asthma-**
65 **controller medicine alone does not control your**
66 **asthma or that you need 2 asthma-controller**
67 **medicines.**

68

69 • **Call your healthcare provider if breathing**
70 **problems worsen over time while using**
71 **SYMBICORT. You may need different**
72 **treatment.**

73

74 • **Get emergency medical care if:**
75 ○ **Breathing problems worsen quickly, and**
76 ○ **You use your short-acting beta₂-agonist**
77 **medicine, but it does not relieve your**
78 **breathing problems.**

79

80

81 **What is SYMBICORT?**

82 SYMBICORT combines an inhaled corticosteroid
83 medicine, budesonide (the same medicine found in
84 PULMICORT TURBUHALER), and a long-acting
85 beta₂-agonist medicine (LABA), formoterol (the same
86 medicine found in FORADIL AEROLIZER).

87

88 SYMBICORT is used long-term, twice a day, everyday
89 to control symptoms of asthma, and prevent symptoms
90 such as wheezing in patients 12 years of age and older.

91
92 **SYMBICORT contains formoterol (the same**
93 **medicine found in FORADIL AEROLIZER).**
94 **Because LABA medicines such as formoterol may**
95 **increase the chance of death from asthma problems,**
96 **SYMBICORT is not for patients with asthma who:**

- 97 ○ are well controlled with another asthma-
- 98 controller medicine such as a low to medium
- 99 dose of an inhaled corticosteroid medicine
- 100 ○ only need short-acting beta₂-agonist medicines
- 101 once in awhile

102
103

104 **What should I tell my healthcare provider**
105 **before using SYMBICORT?**

106 **Tell your healthcare provider about all of your**
107 **health conditions, including if you:**

- 108 ○ **have heart problems**
- 109 ○ **have high blood pressure**
- 110 ○ **have seizures**
- 111 ○ **have thyroid problems**
- 112 ○ **have diabetes**
- 113 ○ **have liver problems**
- 114 ○ **have osteoporosis**
- 115 ○ **have an immune system problem**
- 116 ○ **are pregnant or planning to become pregnant.** It
- 117 is not known if SYMBICORT may harm your
- 118 unborn baby.
- 119 ○ **are breastfeeding.** It is not known if SYMBICORT
- 120 passes into your milk and if it can harm your baby.
- 121 ○ **are allergic to SYMBICORT or any other**
- 122 **medicines**
- 123 ○ **are exposed to chickenpox or measles**

124

125 Tell your healthcare provider about all the medicines
126 you take including prescription and non-prescription
127 medicines, vitamins, and herbal supplements.
128 SYMBICORT and certain other medicines may interact
129 with each other. This may cause serious side effects.

130

131 Know all the medicines you take. Keep a list and show
132 it to your healthcare provider and pharmacist each time
133 you get a new medicine.

134

135

136 **How do I use SYMBICORT?**

137 **See the step-by-step instructions for using**
138 **SYMBICORT at the end of this Medication Guide.**

139 Do not use SYMBICORT unless your healthcare
140 provider has taught you and you understand everything.

141 Ask your healthcare provider or pharmacist if you have
142 any questions.

143

144 • Use SYMBICORT exactly as prescribed. **Do not**
145 **use SYMBICORT more often than prescribed.**
146 SYMBICORT comes in 2 strengths. Your
147 healthcare provider has prescribed the strength that
148 is best for you.

149

150 • SYMBICORT should be taken as 2 puffs in the
151 morning and 2 puffs in the evening every day. If
152 you miss a dose of SYMBICORT, you should take
153 your next dose at the same time you normally do.
154 Do not take SYMBICORT more often or use more
155 puffs than you have been prescribed.

156

157 • Rinse your mouth with water after each dose (2
158 puffs) of SYMBICORT.

159

160 • **While you are using SYMBICORT twice a day,**
161 **do not use other medicines that contain a long-**
162 **acting beta₂-agonist (LABA) for any reason, such**
163 **as SEREVENT DISKUS (salmeterol xinafoate**
164 **inhalation powder), ADVAIR DISKUS or**
165 **ADVAIR HFA (fluticasone propionate and**
166 **salmeterol), or FORADIL AEROLIZER**
167 **(formoterol fumarate inhalation powder).**

168

169 • Do not change or stop any of your medicines used to
170 control or treat your breathing problems. Your
171 healthcare provider will adjust your medicines as
172 needed.

173

- 174 • Make sure you always have a short-acting beta₂-
175 agonist medicine with you. Use your short-acting
176 beta₂-agonist medicine if you have breathing
177 problems between doses of SYMBICORT.
178
- 179 • **Call your healthcare provider or get medical care**
180 **right away if:**
- 181 ○ your breathing problems worsen with
182 SYMBICORT
 - 183 ○ you need to use your short-acting beta₂-
184 agonist medicine more often than usual
 - 185 ○ your short-acting beta₂-agonist medicine
186 does not work as well for you at relieving
187 symptoms
 - 188 ○ you need to use 4 or more inhalations of your
189 short-acting beta₂-agonist medicine for 2 or
190 more days in a row
 - 191 ○ you use 1 whole canister of your short-acting
192 beta₂-agonist medicine in 8 weeks' time
 - 193 ○ your peak flow meter results decrease. Your
194 healthcare provider will tell you the numbers
195 that are right for you.
 - 196 ○ your asthma symptoms do not improve after
197 using SYMBICORT regularly for 1 week.
- 198

199 **What are the possible side effects with**
200 **SYMBICORT?**

201 **SYMBICORT contains formoterol. In patients with**
202 **asthma, LABA medicines such as formoterol may**
203 **increase the chance of death from asthma problems.**

204 See “What is the most important information I should
205 know about SYMBICORT?”

206
207 **Other possible side effects with SYMBICORT**
208 **include:**

209
210 • **serious allergic reactions including rash, hives,**
211 **swelling of the face, mouth, and tongue, and**
212 **breathing problems.** Call your healthcare provider
213 or get emergency medical care if you get any
214 symptoms of a serious allergic reaction.

215
216 • **chest pain**

217

- 218 • **increased blood pressure**
219
220 • **a fast and irregular heartbeat**
221
222 • **headache**
223
224 • **tremor**
225
226 • **nervousness**
227
228 • **immune system effects and a higher chance for**
229 **infections**
230
231 • **eye problems including glaucoma and cataracts.**
232 Regular eye exams should be considered while using
233 SYMBICORT.
234
235 • **lower bone mineral density.** This may be a
236 problem for people who already have a higher
237 chance for low bone mineral density (osteoporosis).
238
239 • **slowed growth in children.** A child's growth
240 should be checked often.
241
242 • **throat irritation.**
243
244 Tell your healthcare provider about any side effect that
245 bothers you or that does not go away.
246
247 These are not all the side effects with SYMBICORT.
248 Ask your healthcare provider or pharmacist for more
249 information.
250
251
252 **How do I store SYMBICORT?**
253 • Store SYMBICORT at room temperature 68°F to
254 77°F (20°C to 25°C). Store with the mouthpiece
255 down.
256 • The contents of your SYMBICORT canister are
257 under pressure. Do not puncture or throw the
258 canister into a fire or incinerator. Do not use or store
259 it near heat or open flame. Storage above 120°F may
260 cause the canister to burst.
261

- 262 • **Keep SYMBICORT and all medicines out of the**
263 **reach of children.**

264

265

266 **General Information about SYMBICORT**

267 Medicines are sometimes prescribed for purposes not
268 mentioned in a Medication Guide. Do not use
269 SYMBICORT for a condition for which it was not
270 prescribed. Do not give your SYMBICORT to other
271 people, even if they have the same condition. It may
272 harm them.

273

274 This Medication Guide summarizes the most important
275 information about SYMBICORT. If you would like
276 more information, talk with your healthcare provider or
277 pharmacist. You can ask your healthcare provider or
278 pharmacist for information about SYMBICORT that
279 was written for healthcare professionals. You can also
280 contact the company that makes SYMBICORT (toll
281 free) at 1-800-236-9933 or visit our website at
282 www.symbicort-us.com.

283

283

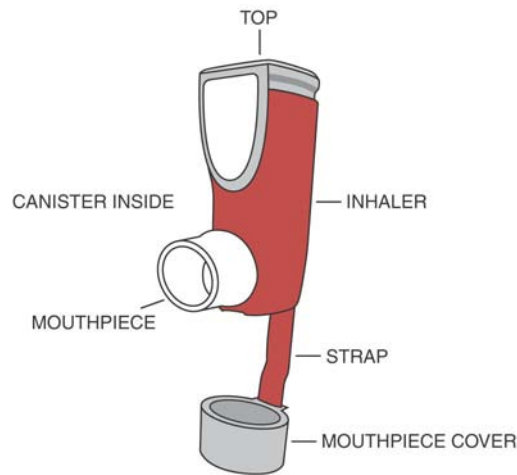


Figure 1

284
285

286 **HOW TO USE SYMBICORT**

287

288 Follow the instructions below for using SYMBICORT.
289 You will breathe-in (inhale) the medicine. If you have
290 any questions, ask your doctor or pharmacist.

291

292 **PREPARING YOUR INHALER FOR USE**

293

294 1. Take your SYMBICORT inhaler out of the
295 moisture-protective foil pouch before you use it
296 for the first time and throw the foil away. Write
297 the date that you open the foil pouch on the dose
298 tracker card that comes with your inhaler. You
299 should discard the inhaler when the labeled
300 number of inhalations have been used or within 3
301 months of opening the foil pouch.

302

303 2. Use the SYMBICORT canister only with the red
304 SYMBICORT inhaler supplied with the product.
305 Parts of the SYMBICORT inhaler should not be
306 used with parts from any other inhalation drug
307 product.

308

309 3. SHAKE THE INHALER WELL for 5 seconds
310 right before each use. Remove the mouthpiece
311 cover. Check the mouthpiece for foreign objects
312 prior to use.

313

314

4. SYMBICORT should be primed before using it for the first time and also when the inhaler has not been used for more than 7 days. Prime the inhaler by shaking the inhaler well for 5 seconds and then releasing a test spray. Then shake the inhaler again and release a second test spray. Your inhaler is now primed and ready for use.

315

316

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318

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322

Do not spray the medicine in your eyes during priming or use.

323

324

325

WAYS TO HOLD THE INHALER FOR USE

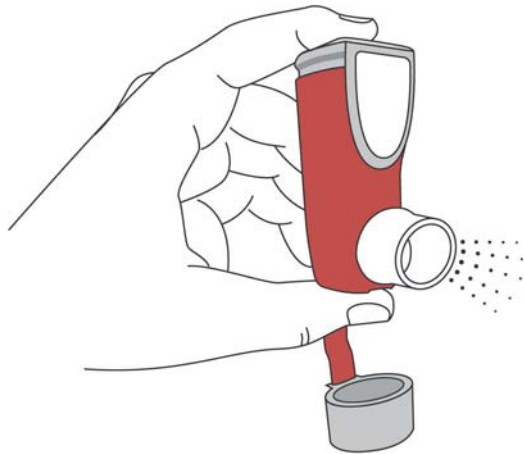


Figure 2

326

327

OR



Figure 3

328

329

330 **USING YOUR SYMBICORT INHALER**

331

332 5. SHAKE THE INHALER WELL for 5 seconds.
333 Remove the mouthpiece cover. Check the
334 mouthpiece for foreign objects.

335

336 6. Breathe out fully (exhale). Raise the inhaler up
337 to your mouth. Place the white mouthpiece fully
338 into your mouth and close your lips around it.
339 Make sure that the inhaler is upright and that the
340 opening of the mouthpiece is pointing towards
341 the back of your throat (see Figure 4).

342

343

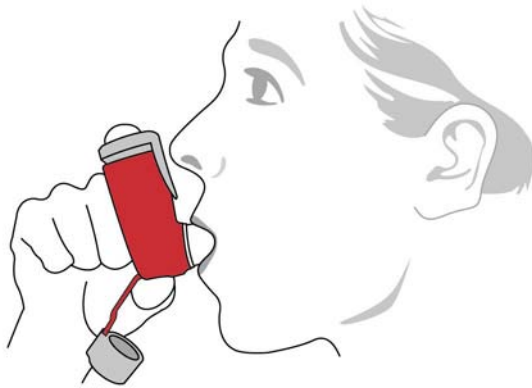


Figure 4

344

345

346 7. While breathing in deeply and slowly through
347 your mouth, press down firmly and fully on the
348 grey top of the inhaler to release the medicine
349 (see Figures 2 and 3).

350

351 8. Continue to breathe in and hold your breath for
352 about 10 seconds, or for as long as is
353 comfortable. Before breathing out, release your
354 finger from the grey top and remove the inhaler
355 from your mouth while keeping the inhaler
356 upright.

357

358 9. Shake the inhaler again for 5 seconds and repeat
359 steps 6 through 8.

360

361 **AFTER USING YOUR SYMBICORT INHALER**

362

363 10. Replace the mouthpiece cover after use.

364

365 11. After you finish taking this medicine (2 puffs),
366 rinse your mouth with water. Spit out the water.
367 Do not swallow it.

368

369 12. Use the enclosed dose tracker card to track the
370 number of puffs you have taken by marking off
371 or punching through each of your morning and
372 evening doses.

373

374 **OTHER IMPORTANT INFORMATION ABOUT** 375 **YOUR SYMBICORT INHALER**

376

377 It is very important that you keep track of the number of
378 inhalations (puffs) you have taken from your
379 SYMBICORT inhaler. Discard SYMBICORT after you
380 have used the number of inhalations on the product
381 label and box. Your inhaler may not feel empty, but you
382 will not get the right amount of medicine if you keep
383 using it.

384

385 SYMBICORT should also be discarded within 3 months
386 after it is taken out of its foil pouch.

387

- 388 • For best results, use and store at room temperature.
389 Avoid exposing product to extreme heat and cold.
390 Store with the mouthpiece down.

391

392 **HOW TO CLEAN YOUR SYMBICORT INHALER**

393 Clean the white mouthpiece of the inhaler every 7 days.

394 To clean the mouthpiece:

395

- 396 • Remove the grey mouthpiece cover
- 397 • Wipe the inside and outside of the white
398 mouthpiece opening with a clean, dry cloth
- 399 • Replace the mouthpiece cover
- 400 • **Do not put the inhaler into water**
- 401 • Do not try to take the inhaler apart

402

403

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405 registered trademarks of the AstraZeneca group of
406 companies. ADVAIR DISKUS, ADVAIR HFA,
407 SEREVENT and DISKUS are registered trademarks of
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410 Corporation.

411

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413

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417

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419

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422

423 This Medication Guide has been approved by the U.S.

424 Food and Drug Administration.