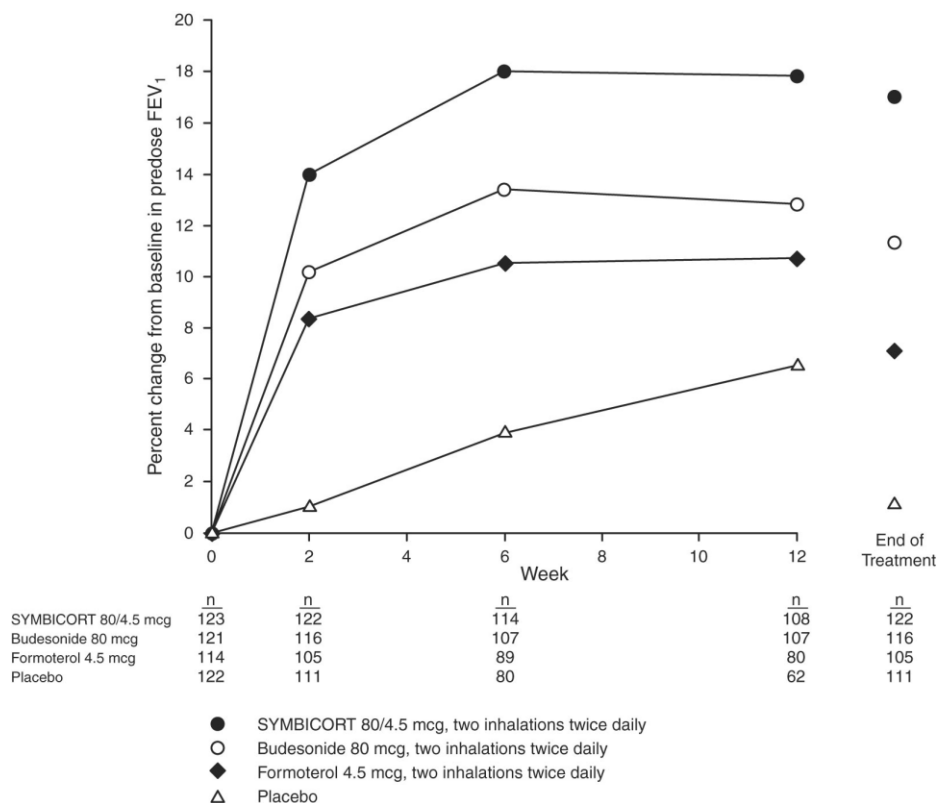


	SYMBICORT 80/4.5 (n=123)	Budesonide 80 mcg (n=121)	Formoterol 4.5 mcg (n=114)	Placebo (n=122)
event ^{1,2}				
Decrease in FEV ₁	3 (2.4)	3 (2.5)	11 (9.6)	9 (7.4)
Rescue medication use	1 (0.8)	3 (2.5)	1 (0.9)	3 (2.5)
Decrease in AM PEF	3 (2.4)	1 (0.8)	8 (7.0)	14 (11.5)
Nighttime awakening ³	17 (13.8)	20 (16.5)	31 (27.2)	52 (42.6)
Clinical exacerbation	1 (0.8)	3 (2.5)	5 (4.4)	20 (16.4)

1. These criteria were assessed on a daily basis irrespective of the timing of the clinic visit, with the exception of FEV₁, which was assessed at each clinic visit.
2. Individual criteria are shown for patients meeting any predefined asthma event, regardless of withdrawal status.
3. For the criterion of nighttime awakening due to asthma, patients were allowed to remain in the study at the discretion of the investigator if none of the other criteria were met.

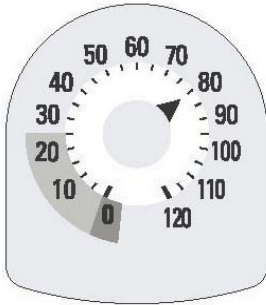
Mean percent change from baseline in pre-dose FEV₁ over 12 weeks is displayed in Figure 2.

Figure 2 Mean Percent Change From Baseline in Pre-dose FEV₁ Over 12 Weeks (Study 2)



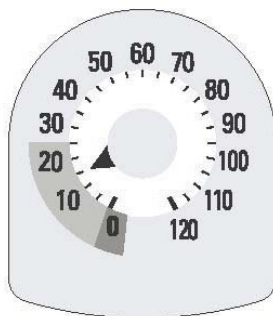
Efficacy results for other secondary end points, including quality of life, were similar to those observed in Study 1.

COUNTER



- The counter will count down each time you release a puff of medicine (either when priming your SYMBICORT inhaler or when taking the medicine).
- When the arrow on the counter approaches 20, you will notice the beginning of a yellow area letting you know that it is time to call your healthcare provider for a refill.

COUNTER



- It is important that you pay attention to the number of inhalations (puffs) left in your SYMBICORT inhaler by reading the counter. Throw away SYMBICORT when the counter shows zero ("0") or 3 months after you take your SYMBICORT inhaler out of its foil pouch, whichever comes first. Your SYMBICORT inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine if you keep using it. Use a new SYMBICORT inhaler and follow the instructions for priming (see instruction 5 above).

How to clean your SYMBICORT inhaler

Clean the white mouthpiece of your SYMBICORT inhaler every 7 days. To clean the mouthpiece:

- Remove the grey mouthpiece cover
- Wipe the inside and outside of the white mouthpiece opening with a clean, dry cloth
- Replace the mouthpiece cover
- **Do not put the SYMBICORT inhaler into water**
- Do not try to take apart your **SYMBICORT** inhaler

Manufactured for: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850
By: AstraZeneca Dunkerque Production, Dunkerque, France
Product of France

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.

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