IRIDIUM

ONCE DAILY
ENERZAIR®
breezhaler®

증상이 조절되지 않는 천식 환자에서 에너제어®의 효과 및 안전성 평가

vs. ICS-LABA

NOVARTIS

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Product Information

※ 처방하시기 전 QR코드 또는 식품의약품안전처의약품통합정보시스템(http://nedrug.mfds.go.kr)을 통해 상세 제품정보를 참조하시기 바랍니다.

에너제어®흡입용캡슐 150/50/80마이크로그램
인다카테롤, 글리코피로니움, 모메타손푸로에이트

에너제어®흡입용캡슐 150/50/160마이크로그램
인다카테롤, 글리코피로니움, 모메타손푸로에이트

ACQ, Asthma Control Questionnaire; **b.i.d.,** twice daily; **CI,** confidence interval; **FEV_1,** forced expiratory volume in one second; **FLU,** fluticasone; **GLY,** glycopyrronium; **ICS,** inhaled corticosteroid; **IND,** indacaterol; **LABA,** long-acting β2-agonist; **LAMA,** long-acting muscarinic antagonist; **MF,** mometasone furoate; **o.d.,** once-daily; **SAL,** salmeterol.

References 1. Kerstjens HAM, et al. *Lancet Respir Med.* 2020;8(10):1000-1012. **2.** 에너제어®흡입용캡슐 식품의약품안전처 의약품통합정보시스템(nedrug.mfds.go.kr). **3.** Kerstjens HAM, et al. *Lancet Respir Med.* 2020;8(10):1000-1012 [Supplementary appendix].

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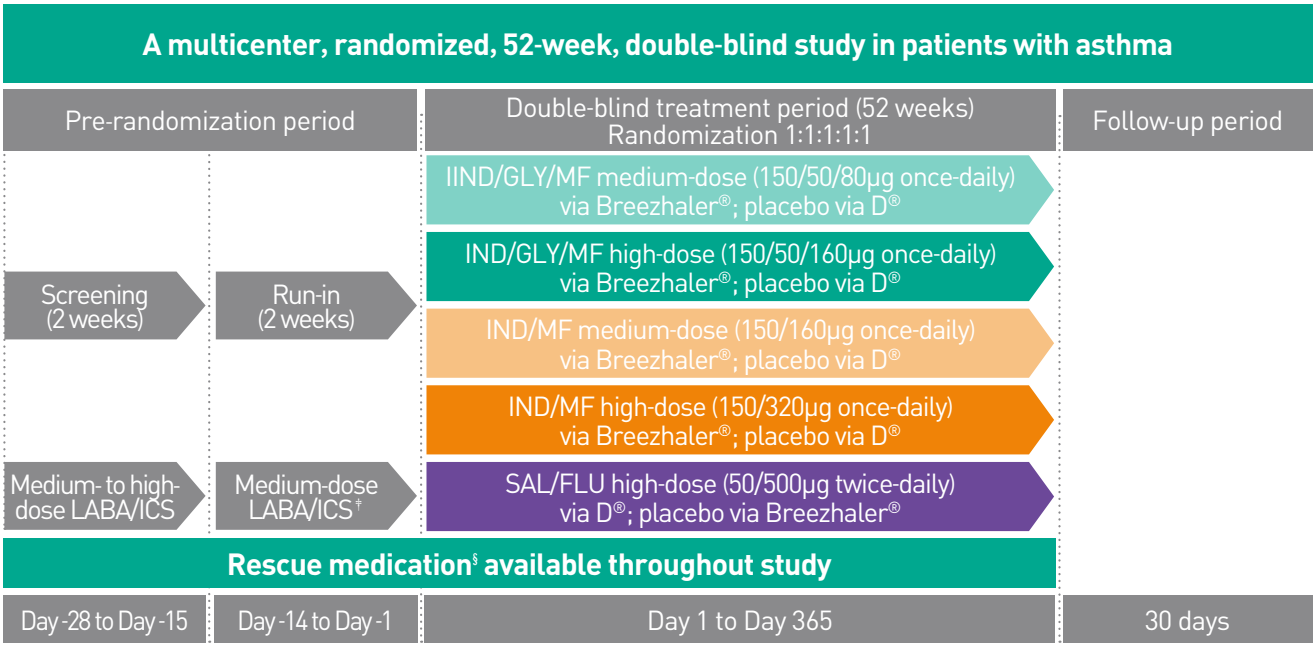
Enerzair® - All in one

에너제어® 최초의 고정용량 3제 복합 천식 치료제[2]

LABA	LAMA	ICS
Indacaterol (150 μg)	**Glycopyrronium** (50 μg)	**Mometasone** (80/160 μg)

Study design

IRIDIUM study는 병용 유지 요법에도 증상이 조절되지 않는 천식 환자에서 ICS-LABA 대비 에너제어®의 효과 및 안전성을 비교 평가한 연구입니다.[1]



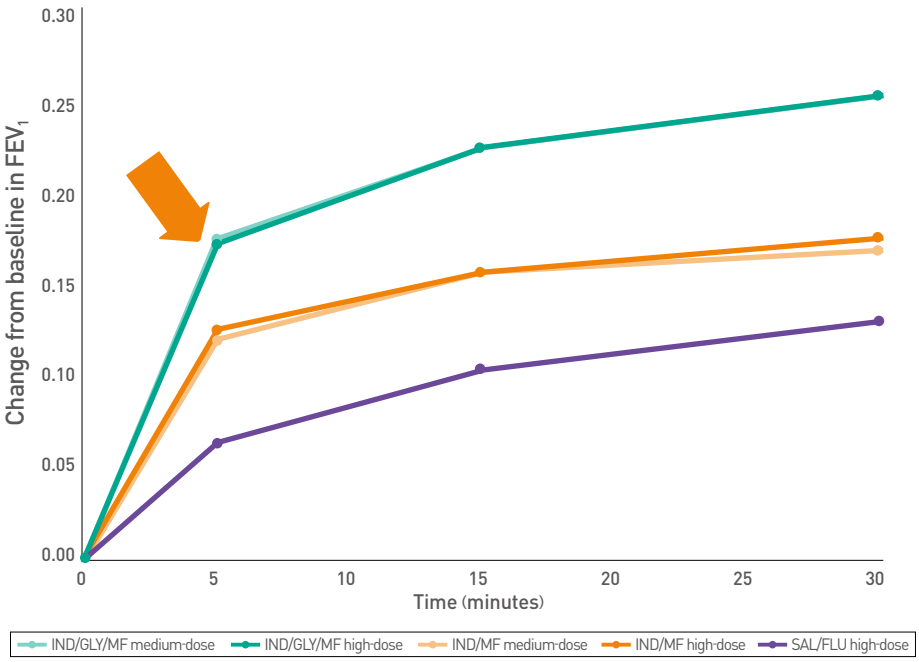
Primary endpoint	Key secondary endpoint
• Change from baseline in trough FEV_1 with MF-IND-GLY vs. MF-IND at week 26	• Change from baseline in ACQ-7 score with either dose of MF–IND–GLY versus the respective dose of MF–IND at week 26.

Study design [IRIDIUM]: In this 52-week, double-blind, double-dummy, parallel-group, active-controlled phase 3 study, patients were recruited from 415 sites across 41 countries. Patients aged 18 to 75 years with symptomatic asthma despite treatment with medium-dose or high-dose ICS-LABA, at least one exacerbation in the previous year, and a percentage of predicted FEV_1 of less than 80% were included. Enrolled patients were randomly assigned (1:1:1:1:1) via interactive response technology to receive medium-dose or high-dose MF-IND-GLY (80 μg, 150 μg, 50 μg; 160 μg, 150 μg, 50 μg) or MF-IND (160 μg, 150 μg; 320 μg, 150 μg) o.d. via Breezhaler, or high-dose fluticasone-salmeterol (FLU-SAL; 500 μg, 50 μg) b.i.d.. The primary outcome was change from baseline in trough FEV_1 with MF-IND-GLY versus MF-IND at week 26. Safety was assessed in all patients who received at least one dose of study drug.

Lung function

고용량 및 중용량의 에너제어®는 고용량의 FLU/SAL 대비 폐기능을 빠르게 개선하였습니다.[1]

FEV$_1$ (5min–1h) with MF–IND–GLY, MF–IND and FLU–SAL at different time points on Day 1 (full analysis set)[3]



Data are presented as LS mean.

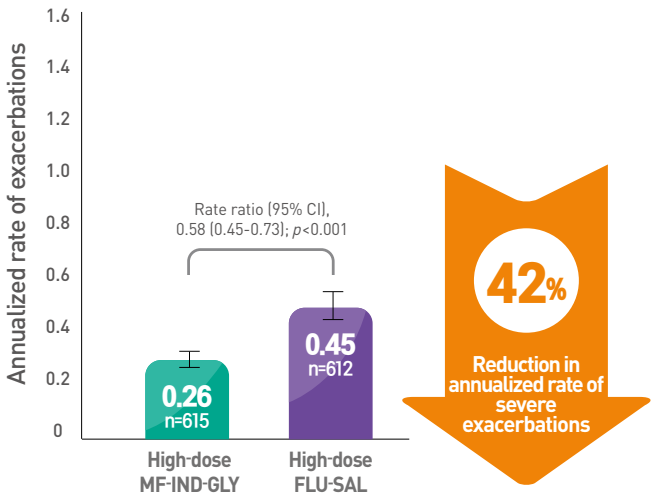
Rapid onset of action

중용량의 에너제어® 투여 5분 후 FEV$_1$이 고용량의 FLU-SAL 대비 개선되었습니다.

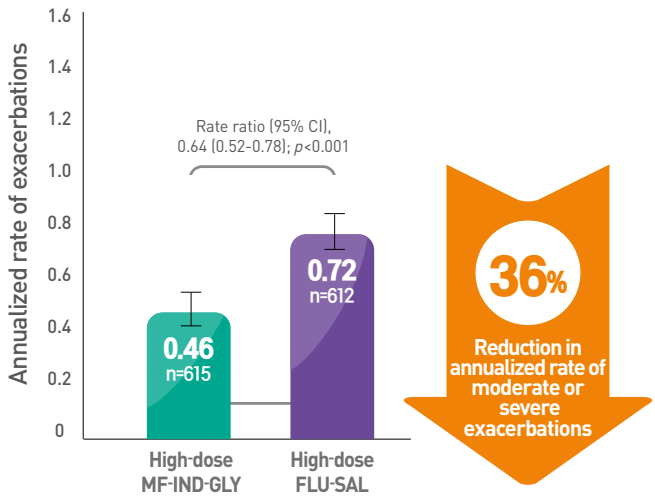
Exacerbations

고용량의 에너제어®는 고용량의 FLU/SAL 대비 중증 악화를 40% 이상 개선하였습니다.[1]

Annualised rate of severe exacerbations at week 52



Annualised rate of moderate or severe exacerbations at week 52



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