OLOMAX® is the first polypill of Olmesartan, Amlodipine and Rosuvastatin combination in Korea developed by Daewoong Pharmaceutical with its own technology.

1. Name of the product : Olomax Tab.

2. Ingredient name

: Olmesartan medoxomil/ Amlodipine/ Rosuvastatin

3. Adaptation : Simultaneous treatment of hypertension and dyslipidemia

4. Usage dose : 1 tablet per day, regardless of meal

5. Content and price.

Texture	Content	Size	Price(KRW)
OAR /5	20/5/5mg	7.3mm	1.032원
OAR /10	20/5/10mg	8.0mm	1,295원
OAR 455	40/5/5mg	8.2mm	1,090원
OAR 451	40/5/10mg	9.2mm	1,347원

Small Pill Size by Evidence

OLOMAX® Tab.
[Olmesartan medoxomil/Amlodipine/Rosuvastatin]
20/5/5mg, 20/5/10mg, 40/5/5mg, 40/5/10mg

FDA U.S. FOOD & DRUG ADMINISTRATION

Size, Shape, and Other Physical Attributes of Generic Tablets and Capsules

Guidance for Industry

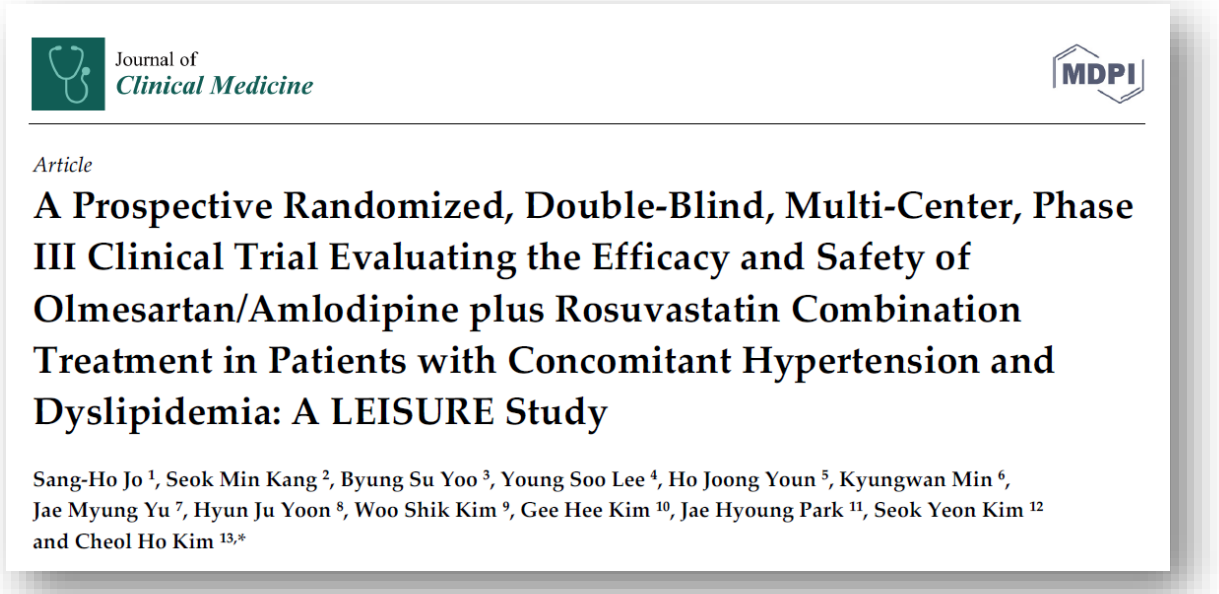
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
June 2015
Pharmaceutical Quality/CMC

Studies in adults evaluating the effect of tablet and capsule size on ease of swallowing suggest that increases in size are associated with increases in patient complaints related to swallowing difficulties at tablet sizes greater than approximately 8 mm in diameter.[13,14,15] The size of the tablet or capsule influences esophageal transit, irrespective of patient factors and administration techniques (i.e., use of fluids, patient position). Smaller tablets generally have been shown to have significantly faster transit times in these studies. Channer and Virjee specifically compared the transit time of 8 mm diameter round tablets to 11 mm diameter round tablets and 14 mm x 9 mm oval tablets and found the transit times for the 8 mm round tablet to be significantly shorter than for 11 mm round and 14 mm x 9 mm oval tablets ($p<.02$ and $p<.04$, respectively).[16] In

<Ref.> US FDA, Guidance for Industry, June 2015

LEISURE study

OLOMAX® Tab.
[Olmesartan medoxomil/Amlodipine/Rosuvastatin]
20/5/5mg, 20/5/10mg, 40/5/5mg, 40/5/10mg



Journal of *Clinical Medicine*

MDPI

Article

A Prospective Randomized, Double-Blind, Multi-Center, Phase III Clinical Trial Evaluating the Efficacy and Safety of Olmesartan/Amlodipine plus Rosuvastatin Combination Treatment in Patients with Concomitant Hypertension and Dyslipidemia: A LEISURE Study

Sang-Ho Jo [1], Seok Min Kang [2], Byung Su Yoo [3], Young Soo Lee [4], Ho Joong Youn [5], Kyungwan Min [6], Jae Myung Yu [7], Hyun Ju Yoon [8], Woo Shik Kim [9], Gee Hee Kim [10], Jae Hyoung Park [11], Seok Yeon Kim [12] and Cheol Ho Kim [13,*]

- Purpose: Evaluation of the treatment effect and safety of the polypill*-administered group in patients with hypertension and dyslipidemia.
  *polypill [Olmesartan(OM)/Amlodipine(AML)/Rosuvastatin(RO)]
- Subject: Patients aged 20 to 80 with hypertension and dyslipidemia.(n=265)
- Method: Multicenter, randomized, double-blind, phase 3 clinical trials.
  Olmesartan 40 mg was taken oral once a day during a lifestyle improvement therapy period of 4 weeks or more and was randomly assigned to OLOMAX ® group (n=106), OM/RO group (n=106), and OM/AML group (n=53) and taken oral once a day for 8 weeks.
- Endpoint
  - 1st endpoint: The amount of change in sitSBP in the OLOMAX® group and OM/RO group compared to the baseline after 8 weeks of administration, and the rate of change in LDL-C in the OLOMAX® group and OM/AM group compared to the baseline after 8 weeks of administration.
  - 2nd endpoint: The amount of change in sitSBP in the OLOMAX® group and OM/AM group compared to the base value, the rate of change in LDL-C in the OLOMAX® group and OM/RO group compared to the base value, the change in sit DBP compared to the base value, and lipid improvement effects.

Ref.> Jo SH, et al. J. Clin. Med. 2022;11(2): https://doi.org/10.3390/jcm11020350