First and only [1,2,*]

For patients with hypercholesterolemia to manage lipid level,[3,4]

Start with Atozet®,

the ***only Atorvastatin+Ezetimibe combination therapy*** *in Korea*[1,#]

Based on 28 February 2020. * Following the application criteria of National Health Insurance Reimbursement, Atozet® is the initial therapy for patients with hypercholesterolemia (first) and the only Atorvastatin+Ezetimibe fixed combination therapy approved in S. Korea as of Feb. 2020. (Only)

References 1. MFDS. Search results for atorvastatin and ezetimibe. Available at <https://nedrug.mfds.go.kr/searchDrug?sort=&sortOrder=false&searchYn=true&page=1&searchDivision=detail&itemName=&entpName=&ingrName1=%EC%95%84%ED%86%A0%EB%A5%B4%EB%B0%94%EC%8A%A4%ED%83%80%ED%8B%B4&ingrName2=%EC%97%90%EC%A0%9C%ED%8B%B0%EB%AF%B8%EB%8C%8C&ingrName3=&itemSeq=&stdrCodeName=&atcCodeName=&indutyClassCode=&sClassNo=&narcoticKindCode=&etcOtcCode=&makeMaterialGb=&searchConEe=AND&eeDocData=&searchConUd=AND&udDocData=&searchConNb=AND&nbDocData=&startPermitDate=&endPermitDate=> Accessed Feb. 28, 2020. **2.** Ministry of Health and Welfare. Details of the application criteria and methods of National Health Insurance Reimbursement (Ministry of Health and Welfare Public No. 2016-66, Apr 29 2016) **3.** Atozet® Prescribing information, MFDS. **4.** Ministry of Health and Welfare. Details of the application criteria and methods of National Health Insurance Reimbursement (Ministry of Health and Welfare Public No. 2014-34, Mar 1 2014).

Atozet®
(ezetimibe and atorvastatin, MSD)

Selected Safety Information ATOZET® (Ezetimibe/Atorvastatin) 10/10, 10/20, 10/40, 10/80 mg

[Indications] ATOZET is indicated to lower total-C, LDL-C, Apo B, TG and increase HDL-C as adjunctive therapy to diet for use in adults with primary (heterozygous familial and non-familial) hypercholesterolaemia or mixed hyperlipidaemia. ATOZET is indicated as adjunctive therapy to diet for use in adults with Homozygous Familial Hypercholesterolaemia to lower LDL-C and total-C. ATOZET may be used as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) in these patients or if such treatments are unavailable. **[Dosage / Direction for Use]** One ATOZET tablet daily (any time of day). The patient should be on an appropriate lipid lowering diet and continue on this diet during or before treatment with ATOZET. The dose should be adjusted by patient's low-density lipoprotein cholesterol (LDL-C) baseline, recommended target level for LDL-C, and response to current cholesterol-lowering therapy. Starting dose 10/10mg or 10/20mg once daily is recommended. In patients who require a larger reduction in LDL-C (≥55%), starting dose 10/40mg is recommended. **[Contraindications]** ATOZET is contraindicated in patients with hypersensitivity to ezetimibe, atorvastatin, or any of its inactive ingredients. Active liver disease or unexplained persistent elevations of serum transaminases. Myopathy. Hereditary disorders such as galactose intolerance, lapp Lactase deficiency, glucose-galactose malabsorption. Pregnancy and nursing. Patients taking glecaprevir or pibrentasvir. **[Warnings]** Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with atorvastatin and with other drugs in this class. Therefore, ATOZET therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., severe acute infection, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders, and uncontrolled seizures). **[Adverse Reactions]** In a placebo-controlled study for ATOZET(ezetimive, atorvastatin), median of administration duration was 12 weeks. Most common adverse reactions causing discontinuation of ATOZET were myalgias(0.8%), abdominal pain(0.8%), hepatic enzyme increased(0.8%), and most common adverse reactions were increased ALT(5%), increased AST(5%), musculoskeletal pain(4%) among 628 patients. **[General precautions]** 1) Myopathy/Rhabdomyolysis: In patients with risk factor(s) for myopathy/rhabdomyolysis, CPK test should be obtained prior to initiating therapy with ATOZET, and ATOZET should be carefully used. Physicians should carefully weigh the potential benefits and risks and should carefully monitor such patients. Reports of myopathy and/or rhabdomyolysis have been observed with HMG-CoA reductase inhibitors coadministered with daptomycin. Caution should be used when prescribing HMG-CoA reductase inhibitors with daptomycin, as either agent can cause myopathy and/or rhabdomyolysis when given alone. Consideration should be given to suspending ATOZET temporarily in patients taking daptomycin. 2) Liver enzymes : Liver enzyme tests should be obtained prior to initiating therapy with ATOZET and repeated as clinically indicated. Patients who develop increased transaminase levels should be monitored until the abnormalities resolve. Should an increase in ALT or AST of >3 times ULN persist, reduction of dose or withdrawal of atorvastatin is recommended. There have been rare postmarketing reports of fatal and non-fatal hepatic failure in patients taking statins, including atorvastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with ATOZET, promptly interrupt therapy. If an alternate etiology is not found, do not restart ATOZET. Revised : 26 January 2021.

※ Before prescribing, please refer to the Prescribing information for further details.

[Importer/Permitholder]
MSD

[Vendor]
ORGANON
50, Jong-ro 1-gil, Jongno-gu, Seoul, 03142, Korea
tel: 1577-8582 https://www.msd-korea.com/organon

[Vendor]
종근당
8, Chungjeong-ro, Seodaemun-gu, Seoul, 03742, Korea
Tel: +82-2-2194-0300 / Fax: +82-2-2194-0369 www.ckdpharm.com

23th 416, Hangang-daero, Jung-gu, Seoul, Korea Tel +82-2-331-2000 http://www.msd-korea.com

KR-ATO-00274 05/2022