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(54)	Title	USE OF EICOSAPENTAENOIC ACID ETHYL ESTER FOR TREATING HYPERTRIGLYCERIDEMIA
(56)	References Cited:	VON SCHACKY CLEMENS: "A review of omega-3 ethyl esters for cardiovascular prevention and treatment of increased blood triglyceride levels.", VASCULAR HEALTH AND RISK MANAGEMENT 2006 LNKD- PUBMED:17326331, vol. 2, no. 3, 2006, pages 251-262, XP002578779, ISSN: 1176-6344 MCKENNEY JAMES M ET AL: "Role of prescription omega-3 fatty acids in the treatment of

hypertriglyceridemia.", PHARMACOTHERAPY MAY 2007 LNKD- PUBMED:17461707, vol. 27, no. 5, May 2007 (2007-05), pages 715-728, XP008115778, ISSN: 0277-0008

RAMBJOR G S ET AL: "Eicosapentaenoic acid is primarily responsible for hypotriglyceridemic effect of fish oil in humans.", LIPIDS MAR 1996 LNKD- PUBMED:8729093, vol. 31 Suppl, March 1996 (1996-03), pages S45-S49, XP000614874, ISSN: 0024-4201

ANONYMOUS: "Epadel Capsules 300 - Drug information brochure (in Japanese)", MOCHIDA PHARMACEUTICAL CO., LTD, January 2000 (2000-01), pages 1-16, XP055260399,

NASA YOSHIHISA ET AL: "Long-term supplementation with eicosapentaenoic acid salvages cardiomyocytes from hypoxia/reoxygenation-induced injury in rats fed with fish-oil-deprived diet", JAPANESE JOURNAL OF PHARMACOLOGY., vol. 77, no. 2, June 1998 (1998-06), pages 137-146, XP055393449, KYOTO, JP ISSN: 0021-5198

KURABAYASHI TAKUMI ET AL: "Eicosapentaenoic acid effect on hyperlipidemia in menopausal Japanese women", OBSTETRICS AND GYNECOLOGY, vol. 96, no. 4, October 2000 (2000-10), pages 521-528, XP055393453, US ISSN: 0029-7844, DOI: 10.1016/S0029-7844(00)00988-1

SHINOZAKI KOJI ET AL: "The long-term effect of eicosapentaenoic acid on serum levels of lipoprotein (a) and lipids in patients with vascular disease", JOURNAL OF ATHEROSCLEROSIS AND THROMBOSIS, vol. 2, no. 2, January 1996 (1996-01), pages 107-109, XP055393438, JP ISSN: 1340-3478

HAYASHI KOZO ET AL: "Decreases In Plasma Lipid Content And Thrombotic Activity By Ethyl Eicosapentate Purified From Fish Oils", CURRENT THERAPEUTIC RESEARCH, vol. 56, no. 1, 1995, pages 24-31, XP002578780, ISSN: 0011-393X

BAYS H E ET AL: "Prescription omega-3 fatty acids and their lipid effects: Physiologic mechanisms of action and clinical implications", EXPERT REVIEW OF CARDIOVASCULAR THERAPY 200803 GB, vol. 6, no. 3, March 2008 (2008-03), pages 391-409, XP002695481, ISSN: 1477-9072

OH ROBERT C ET AL: "Management of hypertriglyceridemia.", AMERICAN FAMILY PHYSICIAN 1 MAY 2007 LNKD- PUBMED:17508532, vol. 75, no. 9, 1 May 2007 (2007-05-01), pages 1365-1371, XP002578781, ISSN: 0002-838X

ANONYMOUS: "Epadel Capsules 300 (English translation of Japanese drug information brochure)", MOCHIDA PHARMACEUTICAL CO., LTD, January 2000 (2000-01), pages 1-20, XP055260418,

NISHIKAWA MASAZUMI ET AL: "Effects of eicosapentaenoic acid (EPA) on prostacyclin production in diabetics: GC/MS analysis of PGI2 and PGI3 levels", METHODS AND FINDINGS IN EXPERIMENTAL AND CLINICAL PHARMACOLOGY., vol. 19, no. 6, July 1997 (1997-07), pages 429-433, XP055393737, ISSN: 0379-0355

Anonymous: "LOVAZA TM (omega-3-acid ethyl esters) Capsules", , August 2007 (2007-08), pages 1-2, XP055589332, internet Retrieved from the Internet:
URL:https://www.accessdata.fda.gov/drugsat_fda_docs/label/2008/021654s021lblR.pdf [retrieved on 2019-05-16]

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PATENTKRAV

1. Sammensetning for anvendelse i behandling av moderat til alvorlig
hypertriglyseridemi hos et individ som har et fastende baselinje-triglyseridnivå på
5 omtrent 500 mg/dl til omtrent 1500 mg/dl,
hvor i sammensetningen omfatter eikosapentaensyre-etyler, ester,
hvor i eikosapentaensyre-etyleren omfatter minst 96 vekt% av alle
fettsyrener som er til stede i sammensetningen, hvor i sammensetningen ikke
inneholder mer enn 4 vekt% av totale fettsyrer som er forskjellig fra
10 eikosapentaensyre-etyler, og sammensetningen inneholder omtrent 0,1 % til
omtrent 0,6 % av minst én fettsyre som er forskjellig fra eikosapentaensyre-etyler
og dokosaheksaensyre, og
hvor i 4 kapsler, som hver inneholder 1 g av sammensetningen, blir
administrert til individet daglig.