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(54) Title **FENFLURAMINE FOR USE IN THE TREATMENT OF DRAVET SYNDROME**

(56) References Cited:

JP-A- H05 310 564

K Gentsch ET AL: "Laboratory Research Fenfluramine Blocks Low-Mg2'-Induced Epileptiform Activity in Rat Entorhinal Cortex", Epilepsia, 1 January 2000 (2000-01-01), pages 925-928, XP055123170, Retrieved from the Internet: URL:http://onlinelibrary.wiley.com/store/1 0.1111/j.1528-1157.2000.tb00273.x/asset/j. 1528-1157.2000.tb00273.x.pdf?v=1&t=hwd6ipv s&s=4597c5b395f43216016ee3e5eea1c52bb7f99d 62 [retrieved on 2014-06-13]

Katholieke Universiteit Leuven, University Hospital Antwerp: "Interim results of a fenfluramine open-label extension study", European Patent Register , 25 May 2017 (2017-05-25), XP002779207, Retrieved from the Internet: URL:https://register.epo.org/application?documentId=E0G7I1QO7348DSU&number=EP1472403 7&lng=en&npl=false
MEADOR K J: "Seizure reduction with fluoxetine in an adult woman with Dravet syndrome", EPILEPSY & BEHAVIOR CASE REPORTS, ELSEVIER BV, NL, vol. 2, 1 January 2014 (2014-01-01), pages 54-56, XP008169941, ISSN: 2213-3232, DOI: HTTP ://DX.DOI.ORG/10.1016/J.EBCR.2014.03.001
Anonymous: "MacReportMedia - Brabant Pharma Reports Two-Year Follow-Up Data From a 19-year Observational Study Using Low-Dose Fenfluramine for the Treatment of Dravet Syndrome", , 25 November 2013 (2013-11-25), XP055123161, Retrieved from the Internet: URL:http://www.macreportmedia.com/ViewSubm ission.aspx?submissionRequest=25655 [retrieved on 2014-06-13]
BERTEN CEULEMANS ET AL: "Successful use of fenfluramine as an add-on treatment for Dravet syndrome", EPILEPSIA, vol. 53, no. 7, 3 May 2012 (2012-05-03), pages 1131-1139, XP055123152, ISSN: 0013-9580, DOI: 10.1111/j.1528-1167.2012.03495.x
CEULEMANS B. ET AL.: "Successful use of Fenfluramine as add-on treatment in Dravet syndrome: a two year prospective follow up", EUROPEAN JOURNAL OF PAEDIATRIC NEUROLOGY, vol. 17, O11-1866, 1 September 2013 (2013-09-01), XP055123344, US ISSN: 1090-3798, DOI: 10.1016/S1090-3798(13)70013-8

PATENTKRAV

1. Formulering omfattende fenfluramin eller et farmasøytisk akseptabelt salt derav for anvendelse ved behandling av Dravet syndrom, hvor behandlingen inkluderer administrering av fenfluramin som monoterapi.

2. Formulering for anvendelse ifølge krav 1, hvor behandlingen omfatter behandling av en pasient diagnostisert med Dravet syndrom, som utviser en mutasjon i ett, noen eller alle gener valgt fra gruppen bestående av SCN1A, SCN1B, SCN2A, SCN3A, SCN9A, GABRG2, GABRD og PCDH19.

3. Formulering for anvendelse ifølge krav 1 eller krav 2, hvor dosen av fenfluramin er mindre enn 0,5 mg/kg/dag til 0,01 mg/kg/dag.