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| (54) | Title | <b>METHODS OF ADMINISTERING AND EVALUATING NITROGEN SCAVENGING DRUGS FOR THE TREATMENT OF HEPATIC ENCEPHALOPATHY</b> |
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| (56) | References Cited: | WO-A1-2010/025303, US-A1- 2010 008 859, US-A1- 2012 220 661, LEE ET AL.: 'Phase 2 comparison of a novel ammonia scavenging agent with sodium phenylbutyrate in patients with urea cycle disorders: Safety, pharmacokinetics and ammonia control' MOLECULAR GENETICS AND METABOLISM vol. 100, no. 3, July 2010, pages 221 - 228, XP027079433 Retrieved from the Internet: <URL:http://www.sciencedirect.com>, STAUCH ET AL.: 'Oral L-ornithine-L-aspartate therapy of chronic hepatic encephalopathy: results of a placebo-controlled double-blind study' JOURNAL OF HEPATOLOGY vol. 28, no. ISSUE, May 1998, pages 856 - 864, XP055250053 Retrieved from the Internet: <URL:http://www.sciencedirect.com>, ENNS ET AL.: 'Survival after Treatment with Phenylacetate and Benzoate for Urea-Cycle Disorders' N ENGL J MED. vol. 356, no. 22, 31 May 2007, pages 2282 - 2292, XP055148817 Retrieved from the Internet: <URL:http://www.nejm.org>, US-A1- 2013 210 914 |
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Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

**Patentkrav**

- 1.** Glyseryl tri[4-fenylbutyrat] (HPN-100) for anvendelse i en fremgangsmåte for behandling av hepatisk encefalopati (HE) i et individ, hvor fremgangsmåten omfatter:
- 5           (a)     å måle et fastende blodammoniakknivå;
- (b)     å sammenligne det fastende blodammoniakknivået med en øvre grense som er normal for blodammoniakk; og
- (c)     administrere glyseryl tri[4-fenylbutyrat] (HPN-100) til individet dersom det fastende blodammoniakknivået er større enn 1,5 ganger den øvre
- 10    grense for normalt blodammoniakk.
- 2.** Glyseryl tri[4-fenylbutyrat] (HPN-100) for anvendelse ifølge krav 1, hvor individet på forhånd har blitt administrert en første dose av glyseryl tri[4-fenylbutyrat] (HPN-100).
- 3.** Glyseryl tri[4-fenylbutyrat] (HPN-100) for anvendelse ifølge krav 2, hvor
- 15    dosen av glyseryl tri[4-fenylbutyrat] (HPN-100) som administreres i trinn (c) er større enn første dose.
- 4.** Glyseryl tri[4-fenylbutyrat] (HPN-100) for anvendelse i en fremgangsmåte for optimalisering av dosen av glyseryl tri[4-fenylbutyrat] (HPN-100) for behandling av hepatisk encefalopati (HE), hvor fremgangsmåten omfatter:
- 20           (a)     å administrere en første dose av glyseryl tri[4-fenylbutyrat] (HPN-100);
- (b)     å måle et fastende blodammoniakknivå;
- (c)     å sammenligne det fastende blodammoniakknivået med den øvre grense som er normal for blodammoniakk for å bestemme hvorvidt dosen av
- 25    glyseryl tri[4-fenylbutyrat] (HPN-100) skal økes, hvor dosen behøver å bli øket dersom det fastende blodammoniakknivået er større enn 1,5 ganger den øvre grense for normalt blodammoniakknivå; og
- (d)     å administrere en andre dose av glyseryl tri[4-fenylbutyrat] (HPN-100) basert på bestemmelsen i (c).
- 30    **5.** Glyseryl tri[4-fenylbutyrat] (HPN-100) for anvendelse ifølge krav 4, ytterligere omfattende et trinn for bestemmelse av den øvre grense for normalt blodammoniakk for individet.

- 6.** Glyceryl tri[4-fenylbutyrat] (HPN-100) for anvendelse ifølge krav 1 eller 4, hvor den øvre grense for normalt blodammoniakk er 35  $\mu\text{mol/l}$ .