(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 November 2015 (05.11.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/165972 A1

(51) International Patent Classification:
A61K 31/122 (2006.01) *A61P 3/00* (2006.01)

(21) International Application Number:
PCT/EP2015/059352

(22) International Filing Date:
29 April 2015 (29.04.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
1450521-8 30 April 2014 (30.04.2014) SE

(71) Applicant: **SWEDISH ORPHAN BIOVITRUM INTERNATIONAL AB** [SE/SE]; S-112 76 Stockholm (SE).

(72) Inventor: **OLSSON, Birgitta**; Ekeberga 2, S-179 62 Stenhamra (SE).

(74) Agent: **BERGH, Johanna**; AWAPATENT AB, Box 45086, S-104 30 Stockholm (SE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

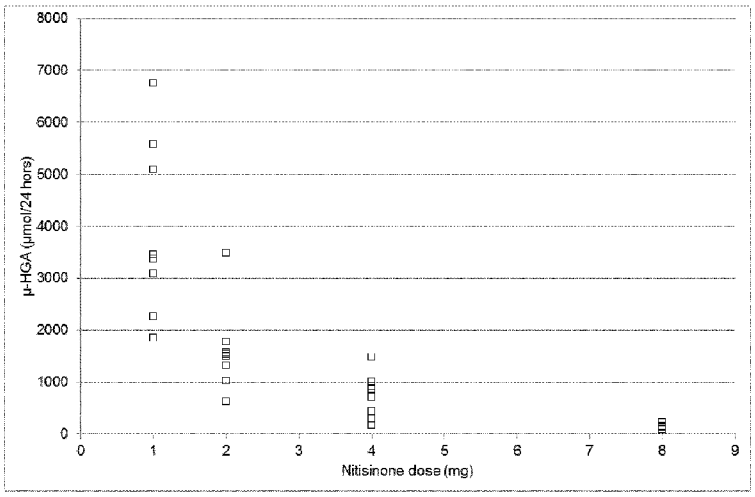
— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: NITISINONE DOSING REGIMENS FOR THE TREATMENT OF ALKAPTONURIA

(57) Abstract: The invention relates to nitisinone (2-[2-nitro-4-(trifluoromethyl)benzoyl]-1,3- cyclohexanedione) for use in the treatment of alkaptonuria, wherein nitisinone is administered in a dose of at least 4 mg per day. The invention also relates to a pharmaceutical composition comprising nitisinone for use in the treatment of alkaptonuria, wherein nitisinone is administered in a dose of at least 4 mg per day.

FIG. 2



WO 2015/165972 A1