



(51) International Patent Classification:

A61K 9/20 (2006.01) A61P 25/00 (2006.01)
A61K 9/28 (2006.01) A61P 43/00 (2006.01)
A61K 31/4453 (2006.01)

(21) International Application Number:

PCT/EP2024/079044

(22) International Filing Date:

15 October 2024 (15.10.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/590,678	16 October 2023 (16.10.2023)	US
63/616,039	29 December 2023 (29.12.2023)	US
24306216.3	18 July 2024 (18.07.2024)	EP
63/679,270	05 August 2024 (05.08.2024)	US

(71) Applicant: **BIOPROJET PHARMA** [FR/FR]; 9 rue Rameau, 75002 PARIS (FR).

(72) Inventors: **CAPET, Marc**; Les Petites Rivières, 35520 MELESSE (FR). **ROBERT, Philippe**; 43 allée des ro-

mantiques, 38100 GRENOBLE (FR). **FINANCE, Olivier**; 19 rue de la Monnaie, 35000 RENNES (FR). **JULIEN, Jean-Stéphane**; 24 rue de Preney, 37540 SAINT CYR SUR LOIRE (FR). **LECOMTE, Jeanne-Marie**; 30 rue des Francs Bourgeois, 75003 PARIS (FR). **SCHWARTZ, Jean Charles**; 9 Villa Seurat, 75014 PARIS (FR). **MELSOPP, Elsie**; 630 W. Germantown Pike Suite 215, PLYMOUTH MEETING, Pennsylvania 19462 (US). **BUDUR, Kumaraswamy**; 630 W. Germantown Pike Suite 215, PLYMOUTH MEETING, Pennsylvania 19462 (US).

(74) Agent: **ROCHER, Olivier** et al.; LAVOIX, 2, place d'Estienne d'Orves, 75441 PARIS CEDEX 09 (FR).

(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, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, MG, MK, MN, MU, 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, ST, SV, SY, TH,

(54) Title: NEW FORMULATIONS OF PITOLISANT AND METHODS OF USE

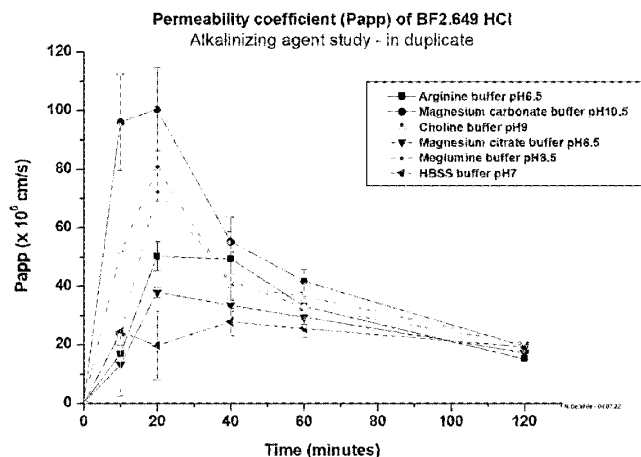


FIG.2

(57) Abstract: An oral dosage form comprising: a core; and a delayed-release coating that surrounds the core, wherein the core comprises pitolisant or a pharmaceutically acceptable salt, solvate, or hydrate thereof; an alkaline agent, and optionally one or more pharmaceutically acceptable excipients. Method to produce said composition. Said composition for use in the therapy.

[Continued on next page]

TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS,
ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, CV, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SC, 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, ME, 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))*
- *in black and white; the international application as filed contained color or greyscale and is available for download from PATENTSCOPE*