

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

(19) World Intellectual Property
Organization
International Bureau

(43) International Publication Date
26 June 2025 (26.06.2025)



(10) International Publication Number
WO 2025/137348 A1

(51) International Patent Classification:

A61K 31/135 (2006.01) A61P 21/00 (2006.01)
A61K 9/00 (2006.01) A61P 29/00 (2006.01)
A61K 9/20 (2006.01)

(21) International Application Number:

PCT/US2024/061125

(22) International Filing Date:

19 December 2024 (19.12.2024)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

63/612,352 19 December 2023 (19.12.2023) US
63/618,892 08 January 2024 (08.01.2024) US

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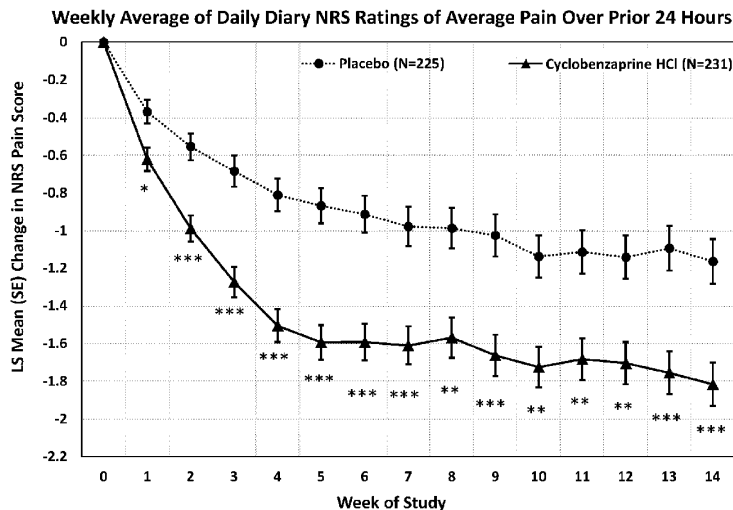
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CV, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IQ, IR, IS, IT, JM, JO, JP, KE, KG,

(54) Title: CYCLOBENZAPRINE HCL FOR USE IN TREATING FIBROMYALGIA WITH EARLY ONSET RESPONSE AND FAVORABLE TOLERABILITY AND SIDE EFFECT PROFILE

Figure 1



(57) Abstract: The present disclosure provides methods for treating or managing fibromyalgia and its associated symptoms in a subject in need hereof characterized by an early onset of one or more of: (1) a reduction in widespread pain characterized by about 0.3 or more difference in the LS mean change in the NRS Pain Score; (2) a reduction in sleep disturbance characterized by about 2.9 or more difference in the LS Mean change in PROMIS Sleep Disturbance T-score; (3) a reduction in fatigue characterized by about 2.0 or more difference in the LS Mean change in PROMIS Fatigue T-score; or (4) an improved sleep quality characterized by about 0.5 or more difference in the LS Mean change in NRS Sleep Quality Score, each as compared to placebo, comprising administering to a subject in need thereof 2.8 mg or 5.6 mg cyclobenzaprine HCl once daily in one or more dosage units by transmucosal administration. The present

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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,
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))
- 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))

disclosure also provides methods for preventing or avoiding one or more of a clinically meaningful change in mean weight, a clinically meaningful change in mean systolic blood pressure or mean diastolic blood pressure, or a decline in sexual functioning in conjunction with treating or managing fibromyalgia or its associated symptoms in a subject in need thereof, the treatment or management being characterized by the transmucosal administration of cyclobenzaprine HCl in one or more dosage units (e.g., a first dosage unit or a second dosage unit). The cyclobenzaprine HCl of these methods is in the form of a mannitol eutectic (e.g., a 75% $\pm$ 2% by weight cyclobenzaprine HCl and 25% $\pm$ 2% by weight β -mannitol eutectic) and the one or more dosage units further comprise a basifying agent.