

CLAIMS

1. A pharmaceutical formulation in the form of a soft gel dosage form, comprising:
a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist or salt or solvate thereof in an amount 0.01-20 weight% of the total weight of the formulation;
a lipophilic phase comprising triglycerides of fatty acids in an amount of 50-80 weight% of the total weight of the formulation; and
at least one lipophilic surfactant comprising partial esters of polyol and fatty acids in an amount of 10-50 weight% of the total weight of the formulation,
wherein the small molecule CGRP receptor antagonist is zavegepant, rimegepant, ubrogepant, atogepant, telcagepant, or olcegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.
2. The pharmaceutical formulation according to Claim 1, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.
3. The pharmaceutical formulation according to Claim 1, wherein the small molecule CGRP receptor antagonist is ubrogepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.
4. The pharmaceutical formulation according to Claim 1, wherein the small molecule CGRP receptor antagonist is atogepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.
5. The pharmaceutical formulation according to any one of Claims 1 to 4, further comprising at least one hydrophilic surfactant with a hydrophilic lipophilic balance ("HLB") above 10 in an amount of 1-30 wt.% of the total weight of the formulation.
6. The pharmaceutical formulation according to any one of Claims 1 to 5, wherein the at least one hydrophilic surfactant is selected from the group consisting of polyoxyethylene (20) monooleate, PEG 8 caprylic/capric glycerides, PEG 6 caprylic/capric glycerides, poly(oxyethylene)(4)Lauryl ether and mixtures thereof.

7. The pharmaceutical formulation according to any one of Claims 1 to 6, wherein the triglycerides of fatty acids are medium chain fatty acids.

8. The pharmaceutical formulation according to any one of Claims 1 to 7, wherein the lipophilic surfactant comprises a mixture of mono and diglyceride of medium chain fatty acids.

9. The pharmaceutical formulation according to any one of Claims 1 to 8, wherein the formulation does not include water.

10. Use of a small molecule CGRP receptor antagonist or salt or solvate thereof in the manufacture of a pharmaceutical formulation for the A-method for treatment or prevention of a condition associated with aberrant levels of CGRP in a subject in need thereof, wherein

the pharmaceutical formulation is to be administered~~method comprises administering to the subject a pharmaceutical formulation~~ in a form of a soft gel dosage form, comprising:

~~a~~the small molecule CGRP receptor antagonist or salt or solvate thereof in an amount 0.01-20 weight% of the total weight of the formulation;

a lipophilic phase comprising triglycerides of fatty acids in an amount of 50-80 weight% of the total weight of the formulation; and

at least one lipophilic surfactant comprising partial esters of polyol and fatty acids in an amount of 10-50 weight% of the total weight of the formulation, wherein the delayed release dosage form is a coated dosage form whose release is pH dependent,

wherein the small molecule CGRP receptor antagonist is zavegepant, rimegepant, ubrogepant, atogepant, telcagepant, or olcegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

11. The ~~method~~use according to Claim 10, wherein the small molecule CGRP receptor antagonist is zavegepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

12. The ~~method~~use according to Claim 10, wherein the small molecule CGRP receptor antagonist is ubrogepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

13. The ~~method~~use according to Claim 11, wherein the small molecule CGRP receptor antagonist is atogepant, a solvate thereof, or a pharmaceutically acceptable salt thereof.

14. The ~~method~~use according to any one of Claims 10 to 13, further comprising at least one hydrophilic surfactant with a hydrophilic lipophilic balance ("HLB") above 10 in an amount of 1-30 wt.% of the total weight of the formulation.

15. The ~~method~~use according to any one of Claims 10 to 14, wherein the at least one hydrophilic surfactant is selected from the group consisting of polyoxyethylene (20) monooleate, PEG 8 caprylic/capric glycerides, PEG 6 caprylic/capric glycerides, poly(oxyethylene)(4)Lauryl ether and mixtures thereof.

16. The ~~method~~use according to any one of Claims 10 to 15, wherein the triglycerides of fatty acids are medium chain fatty acids.

17. The ~~method~~use according to any one of Claims 10 to 16, wherein the lipophilic surfactant comprises a mixture of mono and diglyceride of medium chain fatty acids.

18. The ~~method~~use according to any one of Claims 10 to 17, wherein the formulation does not include water.

19. The ~~method~~use according to any one of Claims 10 to 18, wherein the condition is a disorder selected from acute migraine, chronic migraine, cluster headache, chronic tension type headache, medication overuse headache, post-traumatic headache, post-concussion syndrome, brain trauma, and vertigo.

20. The ~~method~~use according to any one of Claims 10 to 19, wherein the condition is a disorder selected from chronic pain, neurogenic vasodilation, neurogenic inflammation, inflammatory pain, neuropathic pain, diabetic peripheral neuropathic pain, small fiber neuropathic pain, Morton's neuroma, chronic knee pain, chronic back pain, chronic hip pain, chronic finger pain, exercise-induced muscle pain, cancer pain, chronic inflammatory skin pain, pain from burns, pain from scars, complex regional pain syndrome, burning mouth syndrome, alcoholic polyneuropathy, chronic inflammatory demyelinating polyradiculoneuropathy, human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)-associated neuropathy, drug-induced neuropathy, industrial neuropathy, lymphomatous

neuropathy, myelomatous neuropathy, multi-focal motor neuropathy, chronic idiopathic sensory neuropathy, carcinomatous, neuropathy, acute pain autonomic neuropathy, compressive neuropathy, vasculitic/ischaemic neuropathy, tempero-mandibular joint pain, post-herpetic neuralgia, trigeminal neuralgia, chronic regional pain syndrome, eye pain, and tooth pain.

21. The ~~method~~use according to any one of Claims 10 to 18, wherein the condition is a disorder selected from non-insulin dependent diabetes mellitus, vascular disorders, inflammation, arthritis, thermal injury, circulatory shock, sepsis, alcohol withdrawal syndrome, opiate withdrawal syndrome, morphine tolerance, hot flashes in men and women, flushing associated with menopause, allergic dermatitis, psoriasis, encephalitis, ischaemia, stroke, epilepsy, neuroinflammatory disorders, neurodegenerative diseases, skin diseases, neurogenic cutaneous redness, skin rosaceousness, erythema, tinnitus, obesity, inflammatory bowel disease, irritable bowel syndrome, vulvodynia, polycystic ovarian syndrome, uterine fibroids, neurofibromatosis, hepatic fibrosis, renal fibrosis, focal segmental glomerulosclerosis, glomerulonephritis, IgA nephropathy, multiple myeloma, myasthenia gravis, Sjogren's syndrome, osteoarthritis, osteoarthritic degenerative disc disease, temporomandibular joint disorder, whiplash injury, rheumatoid arthritis, and interstitial cystitis.

22. The ~~method~~use according to Claim 21, wherein the skin disease are selected from recurrent herpes, contact hypersensitivity, prurigo nodularis, chronic pruritus, and uremic pruritus.

23. The ~~method~~use according to any one of Claims 10 to 18, wherein the condition is a disorder selected from chronic obstructive pulmonary disease, pulmonary fibrosis, bronchial hyperreactivity, asthma, cystic fibrosis, chronic idiopathic cough, and a toxic injury.

24. The ~~method~~use according to Claim 23, wherein the toxic injury is selected from chlorine gas injury, mustard gas injury, acrolein injury, smoke injury, ozone injury, warfare chemical exposure, and industrial chemical exposure.