

## Annex 1 to the Claimants' Statement of Grounds

### SUMMARY OF THE INVENTION

The present invention provides in one aspect, use of at least one compound selected from melatonin in an effective amount ~~within the range of 0.0025 to 50~~ mg, in the manufacture of a medicament, for improving the restorative quality of sleep, in a patient <sup>aged 55 years or older</sup> suffering from primary insomnia characterized by non-restorative sleep, wherein the medicament is a prolonged release formulation and comprises also at least one pharmaceutical acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers adjuvant or carrier.

In another aspect, the invention provides a medicament, for use in improving the restorative quality of sleep, in a patient <sup>aged 55 years or older</sup> suffering from primary insomnia characterized by non-restorative sleep, wherein the medicament comprises at least one compound selected from melatonin, in an effective amount ~~within the range of 0.0025 to 50~~ mg, in the form of a prolonged release formulation comprising at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifier adjuvant or carrier.

Also described ~~is~~ <sup>is</sup> a method for treating and improving the restorative quality of sleep, in a patient suffering from primary insomnia, which comprises administering an effective amount of at least one compound selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, to said patient, said effective amount being within the range of 0.0025 to 50 mg.

Also described ~~is~~ <sup>is</sup> a medicament, for use in improving both the quality and quantity of sleep, in primary insomnia, which comprises at least one compound selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, and at least one additional therapeutic agent selected from anxiolytics, antidepressants, hypnotics, sedatives, antihypertensives, analgesics, dopaminergic agonists, antipsychotics, minor tranquilizers, anorectics and anti-inflammatory drugs, in addition to at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifiers adjuvant or carrier.

## CLAIMS

1. Use of at least one compound selected from melatonin in an effective amount ~~within the range of 0.0025 to 50~~ mg, in the manufacture of a medicament for improving the restorative quality of sleep, in a patient <sup>aged 55 years or older</sup>/suffering from primary
- 5 insomnia characterized by non-restorative sleep, wherein the medicament is a prolonged release formulation and comprises also at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifier adjuvant or carrier.
- 10 2. Use according to claim 1, wherein said prolonged release formulation includes an acrylic resin.
3. A medicament for use in improving the restorative quality of sleep, in a <sup>aged 55 years or older</sup> patient/suffering from primary insomnia characterized by non-restorative sleep,
- 15 wherein the medicament comprises at least one compound selected from melatonin in an effective amount ~~within the range of 0.0025 to 50~~ mg, in the form of a prolonged release formulation comprising at least one pharmaceutically acceptable diluent, preservative, antioxidant, solubilizer, emulsifier adjuvant or carrier.
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4. Medicament for use according to claim 3, wherein said prolonged release formulation includes an acrylic resin.