CLAIMS

1. Trazodone or a salt thereof for use in a method of treating insomnia in a pediatric population affected by an Intellectual Disability or a Neuro Developmental Disorder (NDD), in a dosage of from 0.2 to 0.6 mg/kg patient.
2. Trazodone for use in a method according to claim 1 wherein the NDD is selected from the group comprising: Autism Spectrum Disorder (ASD), Intellectual disability and Attention Deficit Hyperactivity Disorder (ADHD).
3. Trazodone for use in a method according to any one of claims 1 – 2 wherein said method comprises the administration once a day.
4. Trazodone for use in a method according to any one of claims 1 – 3, wherein said administration is before bedtime.
5. Trazodone for use in a method according to any one of claims 1 – 4 wherein said method comprises the co-administration of at least one drug selected in the group consisting of: first generation antipsychotics, preferably haloperidol, second generation antipsychotics, preferably olanzapine, antidepressants, preferably amitriptyline, benzodiazepines, preferably lorazepam, antiepileptics, preferably gabapentin, mood stabilizers. Preferably lithium, psychostimulants, preferably methylphenidate, antispasmodics, preferably biperiden and atomoxetine.
6. A liquid pediatric pharmaceutical composition comprising trazodone in an amount of from 0.1 to 4% w/V, water and pediatrically acceptable excipients, wherein said pediatrically acceptable excipients provide a Maximum Daily Intake (MDI) lower than the ADI (Acceptable Daily Intake).
7. The pharmaceutical composition according to claim 6 wherein trazodone has a concentration of from 1 % w/V to 3% w/V for use in a method of treating insomnia in a pediatric population affected by

Intellectual Disability or a Neuro Developmental Disorder and providing a dose of from 0.2 to 0.6 mg/kg by drop dilution in a suitable liquid.

8. The pharmaceutical composition according to claim 7 comprising the following excipients: propylene glycol 20-40% w/V, preferably 25-35% w/V, PEG, preferably PEG-400 20-30% w/V, propyl gallate as an antioxidant and citric acid as a buffering agent.
9. The pharmaceutical composition for use according to any one of claims 6-8 wherein the dose is provided by a number of drops comprised from five to thirty of either a 1.5% or 3% w/V trazodone formulation
10. The pharmaceutical composition according to claim 6, in the form of a syrup which comprises trazodone or a salt thereof in a concentration of from 0.1-0.9% w/V.
11. The pharmaceutical composition according to claim 10, wherein the trazodone concentration is of from 0.18 to 0.3% w/V.
12. The pharmaceutical composition according to any one of claims 10-11 further comprising the following excipients: PEG 0-5% w/V, preferably PEG 400 2-4% w/V, glycerol 20-30% w/V, preferably 23-28% w/V, propylen glycol 5-10% w/V, preferably 6-8% w/V and sucrose 30-40% w/V, preferably 33-38% w/V.
13. The syrup according to any one of claims 10-12 for use in a method of treating insomnia in a pediatric population affected by Intellectual Disability or a Neuro Developmental Disorder (NDD) and providing a dosage of from 0.2 to 0.6 mg/kg.
14. A method for treating insomnia in a pediatric patient affected by a Neurodevelopmental Disorder (NDD), comprising administering a trazodone dose of from 0.2 to 0.6 mg/kg patient to said pediatric patient in need thereof.
15. The method according to claim 14, wherein the treatment is chronic.