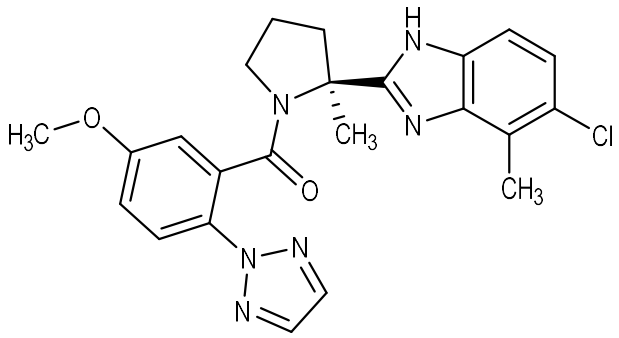
Claims

1. The use of daridorexant:



in free or pharmaceutically acceptable salt form;

in the manufacture of a medicament for the treatment of an insomnia;

wherein said medicament improves the daytime performance of a human subject to whom it is administered,

wherein said improvement of daytime performance is assessed by:

- the IDSIQ daytime sleepiness domain score;

wherein daridorexant, in free or pharmaceutically acceptable salt form, is to be administered in a unit dose of 25 mg ± 10% of daridorexant, or in a unit dose of 50 mg ± 10% of daridorexant;

wherein the duration of the treatment is at least three months.

2. The use of daridorexant in free or pharmaceutically acceptable salt form; in the manufacture of a medicament for the treatment of an insomnia;

wherein said medicament reduces daytime clinical manifestations associated with said insomnia, wherein said daytime clinical manifestations associated with said insomnia are symptoms of daytime sleepiness as assessed by the IDSIQ daytime sleepiness domain score;

wherein daridorexant, in free or pharmaceutically acceptable salt form, is to be administered in a unit dose of 25 mg ± 10% of daridorexant, or in a unit dose of 50 mg ± 10% of daridorexant;

wherein the duration of the treatment is at least three months.

3. The use according to claim 1, wherein said improvement of daytime performance is expressed by human subjects to whom daridorexant has been administered, wherein said subjects feel, cumulatively, less physically tired, less mentally tired, less sleepy and more energetic during the day.

4. The use according to claim 2, wherein said reduction of daytime clinical manifestations associated with said insomnia is expressed by human subjects to whom daridorexant has been administered, wherein said subjects feel, cumulatively, less physically tired, less mentally tired, less sleepy and more energetic during the day.

5. The use according to any one of claims 1 to 4, wherein said treatment of said insomnia results in all of the following treatment effects:

- a decrease in latency to persistent sleep (LPS); and
- a decrease in wake time after sleep onset (WASO); and
- an increase in total sleep time subjectively (sTST) assessed daily by the patient.

6. The use according to claim 5, wherein said medicament is intended for a human subject who has been diagnosed as having difficulties with sleep onset and/or sleep maintenance.

7. The use according to claim 5, wherein said medicament comprises daridorexant in free or pharmaceutically acceptable salt form in a unit dose of 50 mg ± 10% of daridorexant.

8. The use according to claim 7, wherein each of

- said improvement of daytime performance / reduction of daytime clinical manifestations;
- said decrease in latency to persistent sleep (LPS);
- said decrease in wake time after sleep onset (WASO); and
- said increase in total sleep time subjectively (sTST) assessed daily by the patient;

are statistically significant in a clinical endpoint measured at three months of treatment.

9. The use according to any one of claims 1 to 4, wherein daridorexant is in hydrochloric acid salt form.

10. The use according to any one of claims 1 to 4, wherein said medicament is in form of a tablet; wherein said tablet is a film coated tablet comprising

- a tablet core; said tablet core comprising at least two, preferably all of the following excipients: mannitol, microcrystalline cellulose, povidone, croscarmellose sodium, silicon dioxide, and/or magnesium stearate; and
- a film coat; said film coat comprising at least two, preferably all of the following excipients: hypromellose, microcrystalline cellulose, glycerine, talc, titanium dioxide, and/or iron oxide.

11. The use according to any one of claims 1 to 4, wherein said medicament is to be administered within 1 h before bedtime.

12. The use according to any one of claims 1 to 4, wherein said insomnia is a chronic insomnia.

13. The use according to any one of claims 1 to 4, wherein the duration of treatment is three months.

14. The use according to claim 5, wherein the duration of treatment is three months.

15. The use according to claim 7, wherein the duration of treatment is three months.

16. The use according to claim 8, wherein the duration of treatment is three months.