36 Month Surveillance Data Confirms Favorable Safety Profile of a Novel Continuous Release and Absorption Melatonin (CRA-melatonin®) Delivery System

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BACKGROUND

- The cumulative long- term effects of sleep loss have been associated with a wide range of damaging health consequences.[1]
- Melatonin with its soporific effects and benign safety profile has been shown to be an effective sleep aid by decreasing sleep onset latency, increasing total sleep time and improving overall sleep quality.
- Continuous release and absorption melatonin, (CRA-melatonin®), provides continuous release and absorption of melatonin for up to 7 hours.[2]
- There is a medical need for novel, non-pharmacological sleep aid alternatives. The ideal sleep solution would allow sleep to occur with normal sleep architecture and without causing dependence or daytime somnolence.

OBJECTIVE

The objective of the surveillance program (REMSU36 - REMfresh® Safety Update at 36 months) was to collect and report safety surveillance data on a novel CRA-melatonin® delivery system over a 36 - month period.

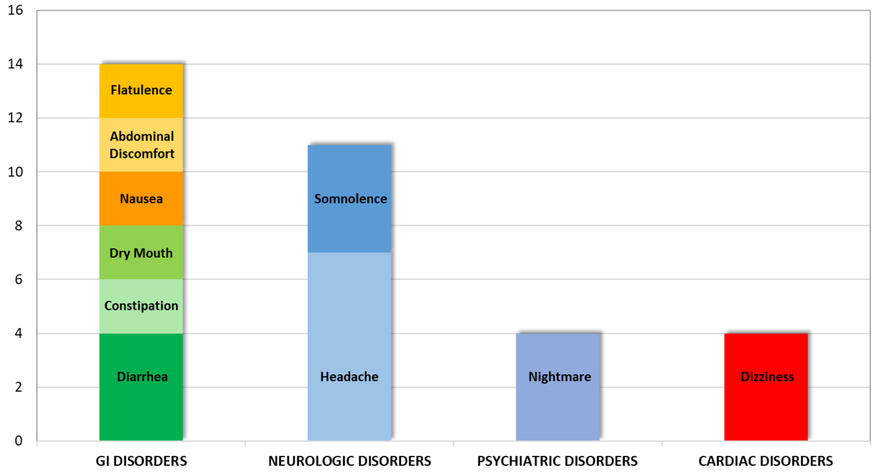
METHODS

- An independent call center with pharmacovigilance-trained health care personnel was retained to receive and record consumer questions, product issues and adverse events with CRA-melatonin®, REMfresh®, (Nestlé HealthCare Nutrition, Bridgewater, NJ).
- The data collection was from March 9th, 2017 to March 9th, 2020.
- An estimated 981,735 adults used CRA-melatonin® during the surveillance period.
- MedDRA were used for coding of adverse events and reactions.
- Events were evaluated as to their relationship to CRA-melatonin® and classified as related, unrelated or cannot be excluded.

RESULTS

- No serious adverse events were reported over 36 months.
- 81 non-serious adverse events were recorded, resulting in a 0.008% of adverse event reporting rate.

Table 1: Most Common AE* by MedDRA System Class and Preferred Term



*2 or more AE classified as cannot be excluded or related

- Of the 81 events, 62 were identified as “cannot be excluded” due to the temporal sequence of events to the consumption of CRA-melatonin®.
- The most common reported adverse events by MedDRA system class were GI disorders (25), nervous system disorders (17), psychiatric disorders (9) and cardiac disorders (7).
- The 5 most common non-serious adverse events reported were headache (7), dizziness (4), somnolence (4), nightmares (4) and diarrhea (4). **Table 1**
- Within the events identified as cannot be excluded, 40% were single, reported occurrences.

CONCLUSION

REMSU36 results are consistent with results observed in previous studies at 12 and 24 months. No serious adverse events and no new risks have been identified with CRA-melatonin® at 36 months. The most common non-serious AE reported are associated with patients suffering from sleep disorders and can be considered as comorbid conditions in the patient population seeking melatonin for sleep support. Somnolence is an expected effect from a sleep aid.

These real-world results are consistent with other melatonin safety and tolerability data reported in the literature. CRA-melatonin® with its extended 7-hour pharmacokinetics profile, continues to be a safe and well tolerated option for individuals seeking a solution for secondary sleep disturbance.

REFERENCES

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