

Melatonin MR-TEVA®

(MELATONIN) MODIFIED RELEASE TABLETS

Melatonin

Consumer Medicine Information

This leaflet provides important information about using Melatonin MR-TEVA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Melatonin MR-TEVA.**

Where to find information in this leaflet:

1. Why am I using Melatonin MR-TEVA?
2. What should I know before I use Melatonin MR-TEVA?
3. What if I am taking other medicines?
4. How do I use Melatonin MR-TEVA?
5. What should I know while using Melatonin MR-TEVA?
6. Are there any side effects?
7. Product details

1. Why am I using Melatonin MR-TEVA?

Melatonin MR-TEVA contains the active ingredient melatonin.

Melatonin MR-TEVA is (not of plant or animal origin), belongs to a group of naturally occurring hormones produced in the body.

Melatonin works by controlling the circadian rhythms and increasing the propensity to sleep.

Melatonin MR-TEVA is used to improve sleep quality and morning alertness in patients over 55 years of age with primary insomnia with poor quality of sleep.

2. What should I know before I use Melatonin MR-TEVA?

Warnings

Do not use Melatonin MR-TEVA if:

- you are allergic to melatonin, or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.
- Do not take Melatonin MR-TEVA if you have been drinking alcohol or intend to drink alcohol or believe that you may have alcohol, in your blood stream.
- Do not take Melatonin MR-TEVA if you are pregnant or breast-feeding. Melatonin MR-TEVA has not been studied in pregnant or breast-feeding women.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Melatonin MR-TEVA talk to your doctor.

Check with your doctor or pharmacist if you:

- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

- take any medicines for any other condition
- you have, or have had the following medical conditions:
 - suffer from liver problems
 - suffer from kidney problems
 - If you suffer from an autoimmune disease
 - have a rare hereditary problem of galactose intolerance, the LAPP lactase deficiency or glucose-galactose malabsorption

Do not give Melatonin MR-TEVA to a child or adolescent. There is no experience with its use in children or adolescents under 18 years old.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Melatonin MR-TEVA and affect how it works.

These include:

- hypnotics and tranquilisers (e.g. benzodiazepine),
- fluvoxamine, thioridazine and imipramine (used to treat depression or psychiatric problems),
- oestrogen (contraceptives or hormone replacement therapy),
- cimetidine and psoralens (used to treat skin problems e.g. psoriasis)
- alcohol
- caffeine

The effect of adding Melatonin MR-TEVA to other medicines used to treat insomnia has not been examined. It is not known if Melatonin MR-TEVA will increase or decrease the effects of other treatments for insomnia.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Melatonin MR-TEVA. They will have more information on medicines to be careful with or avoid while taking Melatonin MR-Teva.