

MELATONIN ARX

Melatonin

Consumer Medicine Information

This leaflet provides important information about using MELATONIN ARX. **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 ARX.**

Where to find information in this leaflet:

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

1. Why am I using MELATONIN ARX?

MELATONIN ARX contains the active ingredient melatonin.

Melatonin is a naturally occurring hormone produced in the body.

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

MELATONIN ARX is used for the short term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 years of age or over

2. What should I know before I use MELATONIN ARX?

Warnings

Do not use MELATONIN ARX 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.
- Do not use in adults or children under 55 years of age.
- Alcohol should not be taken with melatonin. Do not take melatonin if you have been drinking alcohol, intend to drink alcohol or believe that you may have alcohol in your blood stream.

Check with your doctor or pharmacist if you:

- have any other medical conditions:
 - Liver problems
 - Kidney problems
 - An autoimmune disease
 - A hereditary problem of galactose intolerance, LAP lactase deficiency or glucose-galactose malabsorption
- take any medicines for any other condition

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.

- Do not take melatonin if you are pregnant or breast-feeding.

This medicine has not been studied in pregnant or breast-feeding women.

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 and melatonin may interfere with each other. These include:

- hypnotics or tranquilisers (e.g. benzodiazepines)
- certain medicine used to treat mood disorders (e.g. fluvoxamine, thioridazine and imipramine)
- contraceptives or hormone replacement therapy containing oestrogen
- quinolones and rifampicin, used to treat infections
- carbamazepine, used to treat epilepsy
- cimetidine
- psoralens used to treat skin problems (e.g. psoriasis)

- alcohol
- caffeine

Some medicines may interfere with MELATONIN ARX and affect how it works.

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

These medicines may be affected by melatonin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Medicines that may *increase* the effect of MELATONIN ARX include:

- Quinolones
- Fluvoxamine
- 5- or 8—methoxypsoralen
- Cimetidine
- Oestrogens

Medicines that may *reduce* the effect of MELATONIN ARX include:

- Carbamazepine and rifampicin

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 ARX.