

# Syncrodin® 3 mg film-coated tablets

## melatonin

**Read all of this leaflet carefully before you or your child starts taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- Ask your doctor, pharmacist or nurse if you need more information or advice.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as for you or your child.
- If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Syncrodin® is and what it is used for
2. What you need to know before you or your child take Syncrodin®
3. How to take Syncrodin®
4. Possible side effects
5. How to store Syncrodin®
6. Contents of the pack and other information

**1. What Syncrodin® is and what it is used for**

**What Syncrodin® is**  
Syncrodin® is a medicine that contains the active substance melatonin. Melatonin is a hormone produced naturally by the body.

**What Syncrodin® is used for**

- Short-term treatment of jet-lag in adults.
- Treatment of delayed sleep wake phase disorder (DSWPD) in children and adolescents aged 6 to 17 years and adults up to 25 years of age, where healthy sleeping routines have not worked well enough.
- Treatment of sleeplessness (insomnia) in children and adolescents aged 6 to 17 years with attention deficit hyperactivity disorder (ADHD), where healthy sleeping routines have not worked well enough.
- Treatment of sleeplessness (prolonged sleep onset insomnia) in children and adolescents aged 6 to 17 years with autism spectrum disorder (ASD), where healthy sleeping routines have not worked well enough.

*How Syncrodin® works*

- Melatonin is a hormone produced naturally by the body. It helps the body's biological day-and-night rhythm systems to work together. The biological rhythm can be disturbed by travelling across several time zones. This is known as jet-lag. Jet-lag symptoms can happen to you after flying and may include sleeping problems, tiredness during the day, fatigue, mild mental impairment, irritability and problems with the digestive system. These symptoms and how severe they can get vary between individuals, but are generally worse and last longer the more time zones are crossed. Syncrodin® can help to shift the internal body clock to the destination time zone faster and reduce the jet-lag symptoms. You must talk to a doctor if you do not feel better or if you feel worse after 5 days of treatment for jet-lag.
- Syncrodin® helps regulate the body's internal clock, also known as the circadian rhythm. People with delayed sleep wake phase disorder (DSWPD) have difficulty falling asleep at a normal bedtime and tend to stay awake much later than usual. Syncrodin® can help adjust the body's sleep wake cycle by making it easier to fall asleep earlier, reducing the time it takes to drift off to sleep. Syncrodin® is used when healthy sleeping routines, such as regular bedtime and a soothing or relaxing sleeping environment, have not worked well enough.
- Children and adolescents with attention deficit hyperactivity disorder (ADHD) may experience difficulty falling asleep at night. Syncrodin® helps by promoting sleep and reducing the time it takes to fall asleep, making bedtime more manageable. Syncrodin® is used when healthy sleeping routines, such as regular bedtime and a soothing or relaxing sleeping environment, have not worked well enough.
- Children and adolescents with autism spectrum disorder (ASD), may struggle with falling asleep due to differences in how their body regulates melatonin naturally. This can lead to prolonged sleep onset, meaning they take a long time to fall asleep at night. Syncrodin® helps by supporting the body's natural sleep wake cycle, allowing children and adolescents to fall asleep more easily and potentially improving sleep duration. Syncrodin® is used when healthy sleeping routines, such as regular bedtime and a soothing or relaxing sleeping environment, have not worked well enough.

**2. What you need to know before you or your child take Syncrodin®**

**DO NOT take Syncrodin®**

- if you or your child are allergic to melatonin or any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

- Talk to your doctor, pharmacist or nurse before taking Syncrodin® if you or your child:
- have epilepsy. Syncrodin® may increase seizure frequency.
  - have an autoimmune disease (where the body is 'attacked' by its own immune system).
  - have diabetes or impaired glucose tolerance, as this medicine may increase the level of sugar (glucose) in your blood. Please ensure that Syncrodin® is taken at least 2 hours before a meal or at least 3 hours after a meal if you or your child suffer from diabetes.
  - have serious kidney or moderate to serious liver problems.

Please note: This medicine can cause drowsiness.

It is important to let your doctor, pharmacist or nurse know if you or your child have allergies or sensitivities to known allergens. This is to ensure that the medicine prescribed and dispensed containing melatonin is appropriate for patients who are hypersensitive to common allergens.

**Children under 6 years old**

Do not give this medicine to children below the age of 6 years,

as it is not yet known how safe and effective it is for this age group.

**Other medicines and Syncrodin®**

Tell your doctor, pharmacist or nurse if you or your child are taking, have recently taken, or might take any other medicines.

The following medicines may increase the effect of Syncrodin®:

- Fluvoxamine, used for the treatment of depression and obsessive-compulsive disorder.
- Methoxypsoralens, used for the treatment of skin disorders, such as psoriasis.
- Cimetidine, used for the treatment of stomach problems, such as ulcers.
- Oestrogens, used in contraceptives or hormone replacement therapy.
- Quinolones, used in the treatment of bacterial infections.

The following medicines may lower the effect of Syncrodin®:

- Rifampicin, used in the treatment of bacterial infections.
- Carbamazepine, used in the treatment of epilepsy.

Syncrodin® may enhance the sedative effect of:

- Benzodiazepines and non-benzodiazepine hypnotics. These are medicines used to make you feel sleepy, e.g., midazolam, temazepam, zaleplon, zolpidem, and zopiclone. Syncrodin® may also make certain side effects of zolpidem worse, such as morning sleepiness, nausea, confusion.

Syncrodin® may reduce the effect of nifedipine on lowering blood pressure.

Syncrodin® may change the effect of warfarin (used as a blood thinner).

Non-steroidal anti-inflammatory medicines such as acetylsalicylic acid and ibuprofen (used for treating pain and inflammation) may suppress the night-time release of melatonin produced naturally. These medicines should be avoided, especially in the evening.

Beta-blockers (used to control blood pressure) may suppress the night-time release of melatonin produced naturally. These medicines should be taken in the morning.

**Cigarette smoking** lowers the effect of melatonin. This is because it can increase the breakdown of melatonin by the liver, which may make Syncrodin® less effective. Please tell your doctor, pharmacist or nurse if you or your child starts or stops smoking during treatment.

**Syncrodin® with alcohol**

Alcohol can disrupt sleep. It is recommended that alcohol is not consumed while taking this medicine.

**Pregnancy, breast-feeding and fertility**

If you or your daughter are pregnant or breast-feeding, are planning to have a baby, or are possibly already pregnant, ask your doctor, pharmacist or nurse for advice before taking this medicine.

*Pregnancy*

Syncrodin® is not recommended if you or your daughter are pregnant. Melatonin crosses the placenta and it is unclear if there is a risk to the unborn child. If you or your daughter are able to get pregnant you have to use contraception. Talk to your doctor about taking contraceptives simultaneously with this medicine (see section "Other medicines and Syncrodin®").

*Breast-feeding*

Syncrodin® is not recommended if you or your daughter are breast-feeding. Melatonin passes into human milk, and there may be a risk to the breast-fed new-born, infant or child.

*Fertility*

Syncrodin® is not recommended for women and men planning to have a baby, as it is unclear how it affects female and male fertility.

**Driving and using machines**

Syncrodin® may make you less alert for several hours after taking it and may cause drowsiness. Therefore, you or your child should not take this medicine before driving or using machines. If you or your child suffer from continued drowsiness, you should consult your doctor.

**Syncrodin® contains sodium**

Syncrodin® contains less than 1 mmol sodium (23 mg) per tablet, that is to say it is essentially 'sodium-free'.

**3. How to take Syncrodin®**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

**Adults with jet-lag**

*How much to take of this medicine*

The recommended dose for adults and elderly is 3 mg (1 tablet) per day for a maximum of 5 days. If one tablet (3 mg) does not relieve your symptoms, you may take two tablets (6 mg) together. Only take the lowest dose that helps with your symptoms and for the shortest possible time. The maximum daily dose is 6 mg.

*When to take this medicine*

Take your first dose when you arrive at your destination, at the time you normally go to bed.

*How to take this medicine*

Swallow the tablet whole with water. Do not break, crush, or chew the tablet. Always follow your doctor's instructions on how to take this medicine.

*How many times you can take this medicine*

You can take this medicine for a maximum of 16 treatment periods each year.

**Children, adolescents (6 to 17 years) and adults with delayed sleep wake phase disorder (DSWPD)**

*How much to take this medicine*  
The recommended starting dose is 1 mg to 2 mg per day. Your doctor may adjust the dose to find the lowest effective dose that helps with your sleep. Syncrodin® can only be given when 3 mg has been established by your doctor as the lowest effective dose. The maximum daily dose is 5 mg.

*When to take this medicine*  
Take the tablet(s) 1 to 2 hours before the fixed desired bedtime or as advised by your doctor.

*How to take this medicine*  
Swallow the tablet whole with water. Do not break, crush, or chew the tablet. Always follow your doctor's instructions on how to take this medicine.

*How long to take this medicine*  
Your doctor may check after 6 weeks to see if Syncrodin® is helping you sleep. If it is not working, they may stop the treatment. If you feel too sleepy during the day or your sleep pattern is still not right, your doctor might lower the dose or stop it. If the medicine works for you, you will take it for a short time as your doctor recommends. Once your sleep has improved for 6 weeks, your doctor may stop the Syncrodin® to see if you can maintain a regular sleep routine on your own. If your sleep problems return, treatment may restart. Your doctor will review your treatment regularly to ensure it remains suitable for you.

**Children and adolescents aged 6 to 17 years having insomnia with attention deficit hyperactivity disorder (ADHD)**

*How much of the medicine a child or adolescent should take*  
Your doctor will start with the lowest effective dose. Syncrodin® can only be given when 3 mg has been established by your doctor as the lowest effective dose. The dose may be adjusted if needed, but it should not be more than 5 mg per day.

*When to take this medicine*  
Take the tablet(s) 30 to 60 minutes before bedtime.

*How to take this medicine*  
Swallow the tablet whole with water. Do not break, crush, or chew the tablet. Always follow your doctor's instructions on how to take this medicine.

*How long a child or adolescent can take this medicine*  
Your doctor will review the treatment after 3 months to check if Syncrodin® is helping. Regular check-ups will be needed to make sure this treatment is still suitable. If the Syncrodin® is not effective, your doctor may decide to stop it. If it is helping, it will be continued only for as long as necessary. Once a year, your doctor may pause the treatment to check if it is still needed.

**Children and adolescents aged 6 to 17 years having insomnia (prolonged sleep onset) with autism spectrum disorder (ASD)**

*How much of the medicine a child or adolescent should take*  
The recommended starting dose is 1 mg to 2 mg per day. Syncrodin® can only be given by your doctor if the effective dose is 3 mg or a multiple of 3 mg. If the Syncrodin® does not work at the starting dose, the doctor may increase the dose under supervision to 5 mg, up to a maximum of 10 mg per day. However, the lowest effective dose should always be used.

*When to take this medicine*  
Take the tablet(s) 30 to 60 minutes before bedtime.

*How to take this medicine*  
Swallow the tablet whole with water. Do not break, crush, or chew the tablet. Always follow your doctor's instructions on how to take this medicine.

*How long a child or adolescent can take this medicine*  
Your doctor will review the treatment after 3 months to check if Syncrodin® is helping. Regular check-ups will ensure that this medicine remains the right treatment. If the Syncrodin® is not effective, your doctor may adjust the dose or stop treatment. If it is working, it will continue for as short a time as needed. Once a year, treatment may be paused for 5 days to check if it is still necessary.

**Syncrodin® with food**  
Please ensure that Syncrodin® is taken at least 2 hours before a meal or at least 2 hours after a meal. People living with diabetes should ideally wait at least 3 hours.

**If you or your child have taken more Syncrodin® tablets than you should**  
If you or your child took more tablets than recommended and do not feel well, please contact your doctor, hospital or pharmacy as soon as possible. Taking more than the recommended daily dose may make you or your child feel drowsy.

The most common symptoms of overdose are drowsiness, headache, dizziness, and nausea.

**If you or your child forget to take Syncrodin®**  
If you or your child miss a dose at the time advised by your doctor, simply take the next dose as usual. If unsure, ask your doctor, pharmacist or nurse for advice.

DO NOT take a double dose to make up for a missed dose.

**If you or your child stop taking Syncrodin®**  
If you or your child stop taking Syncrodin®, it will not have any harmful effects or withdrawal symptoms. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**  
If you or your child experience any of the following serious side effects you must stop this treatment *immediately* and contact your doctor, pharmacist or nurse:

**Uncommon side effects** (may affect up to 1 in 100 people)

- chest pain

**Rare side effects** (may affect up to 1 in 1000 people)

- reduced number of white blood cells in the blood
- reduced number of blood platelets, which increases the risk of bleeding or bruising
- disorientation
- fainting
- visual impairment, including blurred vision
- feeling your heartbeat ('pounding chest')
- blood (red blood cells) in the urine

**Not known** (frequency cannot be estimated from available data)

- severe allergic reaction resulting in swelling of the tongue or lining of the mouth

**Other side effects**  
If you or your child experience any of the following other side effects contact your doctor, pharmacist or nurse:

**Common side effects** (may affect up to 1 in 10 people)

- headache
- drowsiness

**Uncommon side effects** (may affect up to 1 in 100 people)

- irritability, nervousness, restlessness, abnormal dreams, anxiety
- dizziness
- high blood pressure
- pain in the stomach region, gut or belly, upset stomach, painful regions in the mouth or gums (ulcers), dry mouth, feeling sick
- itching, rash, dry skin
- sugar (glucose) in the urine, increased protein in the urine
- feeling unwell
- weight increase

**Rare side effects** (may affect up to 1 in 1000 people)

- high levels of certain fat molecules (triglycerides) in the blood
- altered mood, aggression, increased sex drive
- memory impairment, restless legs syndrome, 'pins and needles' sensation
- watery eyes
- hot flushes
- vomiting, wind, excess saliva, bad breath, inflammation of the stomach lining
- problems with the nails
- swelling and tenderness of one or more joints (arthritis), sudden and involuntary muscle movement (spasms)
- passing large volumes of urine
- long and possibly painful erection, inflammation of the prostate gland
- thirst
- unusual amounts of electrolytes in the blood

**Not known** (frequency cannot be estimated from available data)

- hypersensitivity reactions
- high amounts of sugar (glucose) in the blood
- flow of milk from the breasts (also in men)

**Reporting of side effects**  
If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You or your representative can also report side effects directly via the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Syncrodin®**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the outer carton and on blister strip(s) after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage condition.
- Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Syncrodin® contains**

- The active substance is melatonin. Each tablet contains 3 mg melatonin.
- The other ingredients are: *tablet core*: maltodextrin, magnesium stearate (E470b), colloid silica anhydrous (E551), microcrystalline cellulose (E460), croscarmellose sodium (E468), *film-coating*: hypromellose (E464).

**What Syncrodin® looks like and contents of the pack**  
Syncrodin® is a white to off-white, clear-coated, round, biconvex tablet of size 7.5 mm.

Syncrodin® pack sizes: available as blister packs of 5, 7, 10, 14, 20, 28, 30 tablets.  
Each blister contains 5, 7, 10, 14, 20 or 30 tablets.

Not all pack sizes may be marketed.

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