Melatonin Consilient Health 1mg/mL oral solution

melatonin

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

WHAT IS IN THIS LEAFLET

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

1. WHAT MELATONIN CONSILIENT HEALTH IS AND WHAT IT IS USED FOR

Melatonin Consilient Health contains the active substance melatonin, which is a hormone produced naturally by the body. The hormone helps regulate the body's day- and night rhythm.

Melatonin Consilient Health can be used for:
- Short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when traveling across several time zones.
- Insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) where healthy sleeping routines has not worked well enough.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MELATONIN CONSILIENT HEALTH

Do not take Melatonin Consilient Health
- if you are allergic to melatonin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Melatonin Consilient Health if you or your child has:
- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood (see section 3).
- liver problems, as Melatonin Consilient Health is not recommended in patients with liver problems.
- kidney problems as caution should be taken when Melatonin Consilient Health is given to patients with kidney problems.
- an autoimmune disease (where the body is "attacked" by its own immune system).
- epilepsy, as Melatonin Consilient Health might increase or decrease the frequency of seizures.
- or if you are elderly.

Melatonin Consilient Health can make you feel drowsy. You should be careful if the drowsiness affects you, as it may impair your ability on tasks such as driving.

Children under 6 years of age
Do not give this medicine to children below the age of 6 years as it has not been tested and its effects are unknown.

Other medicines and Melatonin Consilient Health
Tell your doctor or pharmacist if you or your child is taking, has recently taken or might take any other medicines. These medicines include:

- Fluvoxamine (used for the treatment of depression and obsessive-compulsive disorder)
- Quinolones (for example ciprofloxacin and norfloxacin) and rifampicin (used in the treatment of bacterial infections)
- Cimetidine (used in the treatment of stomach problems such as ulcers)
- Methoxypsoralens (used in the treatment of skin disorders e.g. psoriasis)
- Estrogens (used in contraceptives or hormone replacement therapy)
- Carbamazepine, phenytoin (used in the treatment of epilepsy)
- Theophylline (used in the treatment of asthma)
- Clozapine, haloperidol, olanzapine (used for the treatment of schizophrenia)
- Amitriptyline, imipramine, clomipramine (used for the treatment of depression)
- Ropivacaine (used in the treatment of acute pain)
- Tamoxifen (used in the treatment of breast cancer)
- Caffeine
- Benzodiazepines and non-benzodiazepine hypnotics such as zaleplon, zolpidem and zopiclone (used to induce sleep)
- Nifedipine
- Warfarin

Smoking
Smoking may reduce the effect of Melatonin Consilient Health since it can increase the breakdown of Melatonin Consilient Health by the liver. Tell your doctor if you or your child smoke, start to smoke or quit smoking during treatment.

Melatonin Consilient Health with Alcohol
Do not drink alcohol before, during or after taking Melatonin Consilient Health, because alcohol weakens the effect of the medicine.

Pregnancy, fertility and breast-feeding
If you or your child are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Contraceptives for fertile women and young girls
Fertile women and young girls should use contraceptives under the Melatonin Consilient Health treatment. Since this medicinal product may affect certain contraceptives (see "Other medicines and Melatonin Consilient Health"), the choice of contraceptive should be discussed with a doctor.

Pregnancy
Melatonin Consilient Health is not recommended if you or your child are pregnant. Melatonin Consilient Health crosses the placenta and there is insufficient information on the risk this may pose to the unborn child.

Breast-feeding
Melatonin Consilient Health is not recommended if you are breast-feeding. Melatonin Consilient Health is passed into human breast milk, and a risk to the breast-fed child cannot be excluded.

Driving and using machines
Melatonin Consilient Health may cause drowsiness. If this happens, you must not drive a vehicle, ride a bike or operate machinery.

Melatonin Consilient Health contains methyl parahydroxybenzoate and sodium.
This medicine contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

3. HOW TO TAKE MELATONIN CONSILIENT HEALTH

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults with jet lag
The recommended dose is 1-5 ml (equivalent to 1 to 5 mg) for a maximum of 5 days.
Recommended starting dose: 2 ml (equivalent to 2 mg)
Maximum recommended dose: 5 ml (equivalent to 5 mg) per day, for 5 days.

Take the dose at the time of bedtime at the destination, when traveling over at least 5 time zones, especially for trips in an easterly direction. The oral solution should not be taken before 20:00 hr or after 04:00 hr.

A maximum of 16 treatment cycles may occur per year.

Children and adolescents with ADHD
Recommended starting dose: 1-2 ml (equivalent to 1 to 2 mg) 30-60 minutes before bedtime.
Maximum recommended daily dose: 5 ml (equivalent to 5 mg).

The dose will be adjusted individually to a maximum of 5 ml (equivalent to 5 mg) daily, regardless of age. The lowest dose possible will be given.

Treatment should be followed up regularly by a doctor (at least every 6 months is recommended) to see if it is still appropriate. Treatment should be interrupted once a year to see if treatment is still needed.

Method of administration
Melatonin Consilient Health should be swallowed.

Instruction for use
1. Open the bottle by removing the bottle cap.
2. Insert the syringe into the hole of the integrated adapter in the bottle opening and turn the bottle upside down. Measure the volume the doctor has prescribed by slowly pulling out the plunger. Read the dose on the top of the piston. Turn the bottle right and remove the syringe.
3. You or the child should sit upright when receiving Melatonin Consilient Health. Aim the tip of the syringe at the inside of the cheek. Slowly push in the plunger and allow the child to swallow naturally. Too fast administration of the medicine into the throat can cause discomfort.
4. Clean the inside of the syringe after each use.

Diabetes
If you have or your child has diabetes or impaired glucose tolerance, food should not be consumed 2 hours before or 2 hours after intake of Melatonin, see Warnings and precautions.

If you or your child takes more Melatonin Consilient Health than you/they should
If you or your child has accidentally taken too much medicine, or if for example a child has ingested the medicine by mistake, contact a doctor or pharmacist as soon as possible.

Taking more than the recommended daily dose can make that you or your child feels drowsy.

If you or your child forgets to take Melatonin Consilient Health
If you or your child forgets to take a dose and wake during the night you may take the forgotten dose but at no later than 04:00 in the morning.

Do not take a double dose to make up for a forgotten dose.

If you or your child stops taking Melatonin Consilient Health
There are no known harmful effects if treatment is interrupted or ended. The use of Melatonin Consilient Health is not known to cause any withdrawal effects after treatment completion.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Do not take Melatonin Consilient Health
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you, or your child, experience any of the following serious side effects, tell your doctor immediately and stop taking the medicine.

Frequency not known:
- Hypersensitivity reaction, (allergy like reactions such as itching, difficulties to breath).
- Swelling of deeper layers of skin (angioedema)
- Swelling in mouth and tongue (oedema)

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Other side effects that might occur are listed below.

Common: may affect up to 1 in 10 people
- Headache
- Sleepiness

Uncommon: may affect up to 1 in 100 people
- Irritation, nervousness, restlessness,
- Sleeplessness (insomnia), abnormal dreams, nightmares, night sweats, anxiety, anxious restlessness, physical weakness, lack of energy and enthusiasm,
- Migraine
- Dizziness
- High blood pressure
- Mouth ulceration
- Dry mouth
- Nausea, abdominal pain
- Skin disorders (dermatitis, pruritus, rash, dry skin)
- Pain in arms and legs
- Menopausal symptoms
- Chest pain
- Excretion of glucose in the urine, excess proteins in the urine
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Abnormal liver function tests
- Increased weight

Rare: may affect up to 1 in 1,000 people
- Shingles (herpes zoster)
- Reduced number of white blood cells in the blood
- Reduced number of blood platelets
- Low calcium or sodium levels in the blood
- High level of blood fats
- Changes in mood, aggression, agitation, crying, stress symptoms, feeling confused (disorientation), early morning awakening, increased sex drive (increased libido), depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, uncomfortable sensation in legs (restless legs syndrome), poor quality sleep, tiredness (fatigue)
- Visual impairment, blurred vision, increased tearing
- A feeling of dizziness or spinning (Vertigo), dizziness when standing or sitting
- Faster heartbeats, chest pain due to angina pectoris
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, increased salivation, bad breath, flatulence, abdominal discomfort, inflammation of the stomach lining
- Abnormal dermal sensation (paresthesia), skin disorders (eczema, erythema, psoriasis, rash), nail disorder, sudden feeling of heat (hot flush)
- Pain, arthritis, muscle spasms, neck pain, night cramps,
- Passing large volumes of urine, presence of red blood cells in the urine, need to urinate at night
- Prolonged erection (priapism)
- Inflammation or swelling of prostate gland (prostatitis)
- Thirst
- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests

Not known (reported from use in adults)
- Spontaneous flow of milk from the chest

Additional side effects in children and adolescents
A low frequency of generally mild side effects has been reported. The most common adverse effects were headache, hyperactivity, a feeling of dizziness or “spinning” (vertigo) and abdominal pain. No serious adverse effects have been observed.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via: Yellow Card Scheme, Website: 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 MELATONIN CONSILIENT HEALTH

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 bottle after EXP. The expiry date refers to the last day of that month. Can be used up to 6 months after first opening.
Do not store above 30°C. Store in the original bottle in order to protect from light.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Melatonin Consilient Health contains
- The active substance is melatonin
- The other ingredients are glycerol (E422), sorbic acid, methyl parahydroxybenzoate (E218), sodium hydroxide (for pH adjustments) and purified water.

What Melatonin Consilient Health looks like and contents of the pack
Melatonin Consilient Health is a clear colourless to yellow oral solution.

30 ml, 100 ml, 150 ml, 200 ml solution in an amber glass bottle. The 30 ml, 100 ml, 150 ml & 200 ml bottles with a child-resistant white polypropylene and HDPE/LDPE cap with an integrated syringe adapter. An oral syringe is packed together with the bottle. The capacity of the syringe is 5 ml with scale graduation of 0.2 ml.

Pack size: 1 x 30 ml, 1 x 100 ml, 1 x 150 ml, 1 x 200 ml

Not all pack sizes may be marketed.

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