

APC Labs

Package Leaflet: Information for the patient

Melatonin 8.5mg Transmucosal Buccal Film

Please read this entire leaflet before commencing this medication, as it contains vital information for your benefit.

- Retain this leaflet. You may need to refer to it again.
- Should you have any additional questions, consult your doctor or pharmacist.
- This medication has been prescribed specifically for you. Do not share it with others, as it may cause harm, even if their symptoms are similar to yours.
- If you experience any side effects, discuss them with your doctor or pharmacist. This includes any potential side effects not listed in this leaflet. Refer to Section 4 for further details.

What is in this leaflet:

1. What Melatonin 8.5mg Transmucosal Buccal Film is and what it is used for
2. What you need to know before you take Melatonin 8.5mg Transmucosal Buccal Film
3. How to take Melatonin 8.5mg Transmucosal Buccal Films
4. Possible side effects
5. How to store Melatonin 8.5mg Transmucosal Buccal Films
6. Contents of the pack and other information

1. What Melatonin 8.5mg Transmucosal Buccal Film is, and what is it used for?

The active substance of Melatonin 8.5mg Transmucosal Buccal Film, melatonin, belongs to a natural group of hormones produced by the body.

Melatonin 8.5mg Transmucosal Buccal Film is used on its own for the short-term treatment of primary insomnia (persistent difficulty in getting to sleep or staying asleep, or poor quality of sleep) in patients aged 55 years and older. 'Primary' means that the insomnia does not have any identified cause, including any medical, mental or environmental cause.

This product will be referred to as 'this medicine' in the remainder of the PIL.

2. What you need to know before you take Melatonin 8.5mg Transmucosal Buccal Film

Do not take Melatonin 8.5mg Transmucosal Buccal Film

- 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 taking this medicine.

- If you suffer from liver or kidney problems. No studies on the use of this medicine in

people with liver or kidney diseases have been performed; you should speak to your doctor before taking this medicine, as its use is not recommended.

- If you have been told you suffer from an autoimmune disease (where the body is 'attacked' by its own immune system). No studies on the use of this medicine in people with autoimmune diseases have been performed; therefore, you should speak to your doctor before taking this medicine, as its use is not recommended.

- This medicine 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.

- Smoking may make this medicine less effective because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

Children and adolescents

Do not give this medicine to children between the ages of 0 and 18 years, as it has not been tested, and its effects are unknown.

Other medicines and Melatonin 8.5mg Transmucosal Buccal Film

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. These medicines include:

- Fluvoxamine (used for the treatment of depression and obsessive-compulsive disorder),
- Psoralens (used in the treatment of skin disorders, e.g. psoriasis),
- Cimetidine (used in the treatment of stomach problems such as ulcers),
- Quinolones and rifampicin (used in the treatment of bacterial infections),
- Oestrogens (used in contraceptives or hormone replacement therapy) and
- Carbamazepine (used in the treatment of epilepsy).
- Adrenergic agonists/antagonists (such as certain types of medicines used to control blood pressure by constricting blood vessels, nasal decongestants, blood pressure lowering medicines),
- Opiate agonists/antagonists (such as medicinal products used in the treatment of drug addiction),
- Prostaglandin inhibitors (such as nonsteroidal anti-inflammatory medicines), antidepressant medication, tryptophan and alcohol.
- Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone)
- Thioridazine (for the treatment of schizophrenia) and imipramine (for the treatment of depression).

Melatonin 8.5mg Transmucosal Buccal Film with food, drink and alcohol

Take this medicine after you have eaten. Do not drink alcohol before, during or after taking this medicine because it reduces the effectiveness of this medicine.

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, think you may be pregnant, trying to become pregnant or breastfeeding. Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine may cause drowsiness. If you are affected, you should not drive or operate machinery. If you suffer from continued drowsiness, then you should consult your doctor.

3. How to take Melatonin 8.5mg Transmucosal Buccal Films

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

The recommended dose is one 8.5mg transmucosal film placed against the inside of the cheek after food, before bedtime. This dosage may be continued for up to thirteen weeks.

How to Administer the Transmucosal Film

Did you know there is a more efficient way to get medicines into your bloodstream? It's a method that uses a transmucosal buccal film to deliver the drug through the buccal mucosa and straight into the bloodstream. This video will show you how to use transmucosal buccal film.

When we talk about buccal mucosa we are referring to the inside of the mouth. But unlike regular tablets and capsules, which you swallow, you attach the film to the inside of the mouth, where as soon as it makes contact with the inside of the cheek, it sticks to it immediately and begins to dissolve. Let's go through the process now.

1. The first step before removing the film is to wash your hands and thoroughly dry them to make sure the film doesn't stick to your fingers.
2. Then carefully peel off the film and, with your fingertip, position it on the inside of the cheek.
3. You will feel that the film immediately sticks to the side of the mouth and starts to dissolve.
4. Try not to swallow any saliva while the film is dissolving. The whole purpose of buccal administration is to allow it to dissolve across the inner lining of the mouth into the bloodstream.
5. Do not eat or drink anything for up to an hour before and after applying the film.
6. The film should dissolve in less than two minutes and may leave a slight aftertaste, depending on your prescribed transmucosal film.
7. Remember to seal the plastic blister tray to prevent exposure of the film to air and either return to the silver foil envelope or store in a dark cupboard at room temperature.

You should not swallow the transmucosal film. This medicine should not be crushed or cut in half.

If you take more Melatonin 8.5mg Transmucosal Buccal Film than you should

If you have accidentally taken too much of your medicine, contact your doctor or pharmacist immediately.

Taking more than the recommended daily dose may make you feel drowsy.

If you forget to take Melatonin 8.5mg Transmucosal Buccal Film

If you forget to take your tablet, take another as soon as you remember, before going to sleep, or wait until it is time to take your next dose, then go on as before.

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

If you stop taking Melatonin, 8.5mg Transmucosal Buccal Film

There are no known harmful effects if treatment is interrupted or ended early. The use of this medicine is not known to cause any withdrawal effects after treatment completion.

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

4. Possible side effects

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

If you experience any of the following serious side effects, stop taking the medicine and contact your doctor immediately:-

Uncommon: (may affect up to 1 in 100 people)

Chest pain

Rare: (may affect up to 1 in 1000 people)

- Loss of consciousness or fainting
- Severe chest pain due to angina
- Feeling your heartbeat
- Depression
- Visual impairment
- Blurred vision
- Disorientation
- Vertigo (a feeling of dizziness or “spinning”)
- Presence of red blood cells in the urine
- Reduced number of white blood cells in the blood
- Reduced blood platelets, which increases the risk of bleeding or bruising
- Psoriasis

If you experience any of the following non-serious side effects, contact your doctor and seek medical advice:-

Uncommon: (may affect up to 1 in 100 people)

Irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety, migraine, headache, lethargy (tiredness, lack of energy), restlessness associated with increased activity, dizziness, tiredness, high blood pressure, upper abdominal pain, indigestion, mouth ulceration, dry mouth, nausea, changes in the composition of your blood, which could cause yellowing of the skin, or eyes, inflammation of the skin, night sweats, itching, rash, dry skin, pain in extremities, menopausal symptoms, feeling of weakness, excretion of glucose in the urine, excess proteins in the urine, abnormal liver function and weight increase.

Rare: (may affect up to 1 in 1000 people)

Shingles, high level of fatty molecules in the blood, low serum calcium levels in the blood, low sodium levels in the blood, altered mood, aggression, agitation, crying, stress symptoms, early morning awakening, increased sex drive, depressed mood, memory impairment, disturbance inattention, dreamy state, restless legs syndrome, poor quality sleep, ‘pins and needles’ feeling, watery eyes, dizziness when standing or sitting, hot flushes, acid reflux, stomach disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, gastric disorder, inflammation of the stomach lining, eczema, skin rash, hand dermatitis, itchy rash, nail disorder, arthritis, muscle spasms, neck pain, night cramps, prolonged erection that might be painful, inflammation of the prostate gland, tiredness, pain, thirst, passing large volumes of urine, urinating during the night, increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests.

Frequency not known: (cannot be established from the available data)

Hypersensitivity reaction, swelling of mouth or tongue, swelling of the skin and abnormal milk

secretion.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 8.5mg Transmucosal Buccal Films

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiration date stated on the carton (EXP). The expiry date refers to the last day of that month.

Store this medicine in the plastic blister tray you received it in. Make sure the blister tray is closed after use.

Store in the original package in order to protect it 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 8.5mg Transmucosal Buccal Film contains

The active substance is melatonin. Each transmucosal buccal film contains 8.5 mg of melatonin.

The other ingredients are bitterness reducing agent, microcrystalline cellulose, menthol crystals, sucralose, glycerin, purified water, Nova film Gel Base.

What does Melatonin 8.5mg Transmucosal Buccal Film look like and what contents of the pack

This medicine is available in dark blue or indigo films. There are ten transmucosal films in each blister.

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Company Contact Details

APC Labs Limited

Address

Unit 2 Hamble Court Business Park, Hamble Lane, Hamble-Le-Rice, Hampshire, Southampton, SO31 4QL

Telephone

+44 023 8017 5725

Website

<http://www.apclabs.co.uk>

Medical Information e-mail

info@apclabs.co.uk