

Package leaflet: Information for the patient

Adaflex 1 mg tablets

Adaflex 2 mg tablets

Adaflex 3 mg tablets

Adaflex 4 mg tablets

Adaflex 5 mg tablets

melatonin

Read all of this leaflet carefully before you 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, pharmacist or nurse.
- This medicine has been prescribed for you 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Adaflex is and what it is used for

The active substance of Adaflex, melatonin, belongs to a group of natural hormones produced by the body. The hormone helps regulate the body's day- and night rhythm.

Adaflex is used for:

- Short-term treatment of jet lag in adults. Jet lag refers to the symptoms caused by the time difference when travelling across several time zones.
- Insomnia in children and adolescents (6 to 17 years old) with ADHD, where other healthy sleeping routines have not worked well enough.

2. What you need to know before you take Adaflex

Do not take Adaflex:

- 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, pharmacist or nurse before taking Adaflex if you have:

- diabetes or impaired glucose tolerance, as this medicine may increase the level of glucose in your blood
- liver or kidney problems
- an autoimmune disease (where the body is 'attacked' by its own immune system)
- epilepsy
- or if you are elderly

Adaflex can make you feel drowsy. You should be careful if the drowsiness affects you, as it

may impair your ability to perform tasks such as driving.

Smoking

Smoking may reduce the effects of Adaflex. If you smoke, start to smoke or quit smoking, your doctor may need to adjust your dose.

Adaflex with food and alcohol

Food should not be consumed 2 hours before or 2 hours after intake of Adaflex tablets. Do not drink alcohol in connection with taking Adaflex, as it may reduce the effect of melatonin on sleep.

Children and adolescents

Adaflex should not be given to children below the age of 6 years.

Other medicines and Adaflex

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

If Adaflex is taken at the same time as the following medicines, it can affect the way that Adaflex or the other medicine works:

- Depression (e.g. fluvoxamine, citalopram)
- Sleep disorder (e.g. zolpidem)
- Epilepsy (carbamazepine, phenytoin)
- Ulcers (cimetidine, omeprazole, lansoprazole)
- Skin disorders (psoralens)
- Heart conditions (verapamil)
- High blood pressure (nifedipine, beta-blockers)
- Bacterial infections (rifampicin, ciprofloxacin and norfloxacin)
- Prevention and treatment of blood clots (warfarin)
- Contraceptives containing ethinylestradiol and gestagen
- Hormone replacement therapy due to menopause problems
- Pain and inflammation (non-steroidal anti-inflammatory medicines, e.g. Aspirin (acetylsalicylic acid) and ibuprofen)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should not use Adaflex.

Pregnancy

Adaflex tablets are not recommended if you are pregnant. Melatonin crosses the placenta and there is insufficient information on the risk this may pose to the unborn child. If you are a woman of childbearing potential you have to use contraception.

Breast-feeding

Adaflex tablets are not recommended if you are breast-feeding. Melatonin is excreted in human milk, and a risk to the breast-fed child cannot be excluded.

Fertility

Adaflex tablets are not recommended in women and men planning to have a baby as there is insufficient information on the effects of melatonin on female and male fertility.

Driving and using machines

Adaflex can make you feel drowsy. If this happens, you must not drive or operate machinery.

3. How to take Adaflex

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

If you have impaired kidney function or are elderly, your doctor may need to reduce your dose.

Adults with jet lag

The recommended dose is 1 to 5 mg for a maximum of 5 days.

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

Adaflex for treatment of jet lag may be taken for a maximum of 16 treatment periods per year.

Children and adolescents aged 6-17 years old with ADHD with insomnia

The recommended starting dose is 1 to 2 mg 30-60 minutes before bedtime. If there is no improvement in your/your child's symptoms, your doctor may increase the dose of Adaflex to find the most suitable dose for you/your child. The maximum daily dose that you/your child will receive is 5 mg.

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.

The tablet can be crushed before intake and mixed with water.

Food should not be consumed 2 hours before or 2 hours after intake of Adaflex tablets.

If you take more Adaflex than you 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, hospital or pharmacist as soon as possible.

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

If you forget to take Adaflex

If you forget to take a dose at bedtime and wake during the night you may take the forgotten dose but at no later than 04:00 hr.

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

If you stop taking Adaflex

There are no known harmful effects if treatment is interrupted or ended. The use of Adaflex 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, pharmacist or nurse.

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 Adaflex and contact a doctor immediately:

- Hypersensitivity reaction, swelling of face, swelling of mouth, swelling of tongue
- Chest pain

Common side effects: may affect up to 1 in 10 people

- Headache
- Sleepiness

Uncommon side effects: may affect up to 1 in 100 people

- Irritability, nervousness, restlessness, anxiety
- Insomnia, abnormal dreams, nightmares
- Migraine, dizziness, nausea
- Lethargy (tiredness) and lack of energy, restlessness associated with increased activity
- High blood pressure
- Abdominal pain, indigestion, mouth ulceration, dry mouth
- Changes in the composition of your blood which can cause yellowing of the skin and eyes
- Inflammation of the skin, itching, rash, dry skin, night sweats
- Pain in arms and legs
- Excretion of glucose in the urine, excess proteins in the urine
- Menopausal symptoms
- Feeling of weakness, chest pain
- Weight gain

Rare side effects: may affect up to 1 in 1000 people

- Shingles
- 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
- Altered mood, aggression, restlessness associated with increased activity, crying, stress symptoms, disorientation, early morning awakening, increased sex drive, depressed mood, depression
- Fainting, memory impairment, disturbance in attention, dreamy state, restless legs syndrome, poor quality sleep, ‘pins and needles’ feeling, hallucinations
- Visual impairment, blurred vision, watery eyes
- Vertigo (a feeling of dizziness or “spinning”), dizziness when standing or sitting
- Chest pain due to angina, feeling your heartbeat
- Hot flushes
- Acid reflux, gastrointestinal disorder, blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, inflammation of the stomach lining
- Eczema, skin rash, hand dermatitis, itchy rash, psoriasis, nail disorder
- Arthritis, muscle spasms, neck pain, night cramps
- Passing large volumes of urine, urinating during the night, presence of red blood cells in the urine
- Prolonged erection - that might be painful - without sexual stimulation, inflammation of the prostate gland
- Tiredness, pain, thirst
- Increased liver enzymes, abnormal blood electrolytes and abnormal laboratory tests

Frequency not known: cannot be established from the available data

- Hypersensitivity reaction, swelling of face, swelling of mouth, swelling of tongue
- Abnormal milk secretion
- Hallucinations (e.g. seeing, feeling or hearing things that don’t exist)
- High blood glucose level

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 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 Adaflex

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. 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 medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Adaflex contains

- The active substance is melatonin 1 mg, 2 mg, 3 mg, 4 mg or 5 mg.
- The other ingredients are cellulose, microcrystalline, calcium hydrogen phosphate dihydrate and magnesium stearate.

What Adaflex looks like and contents of the pack

Adaflex 1 mg is a white, round, biconvex tablet with "1" marked on one side, tablet size 9.5 x 3.8 mm.
Adaflex 2 mg is a white, round, biconvex tablet with "2" marked on one side, tablet size 9.5 x 3.8 mm.
Adaflex 3 mg is a white, round, biconvex tablet with "3" marked on one side, tablet size 9.5 x 3.8 mm.
Adaflex 4 mg is a white, round, biconvex tablet with "4" marked on one side, tablet size 9.5 x 3.8 mm.
Adaflex 5 mg is a white, round, biconvex tablet with "5" marked on one side, tablet size 9.5 x 3.8 mm.

Adaflex is available in bottle packs of 30 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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AGB-Pharma AB
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Manufacturer
Legosan AB
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