

MODAFINIL MYLAN

Modafinil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MODAFINIL MYLAN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MODAFINIL MYLAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MODAFINIL MYLAN is used for

MODAFINIL MYLAN is used to improve wakefulness in people with excessive daytime sleepiness associated with the medical condition known as narcolepsy or with Obstructive Sleep Apnoea/Hypopnoea Syndrome (OSAHS), or shift work sleep disorder (SWSD).

In narcolepsy, there is a sudden and irresistible tendency to fall asleep during normal waking hours. This happens at unpredictable times, even when it is inappropriate or may be unsafe to do so. MODAFINIL MYLAN decreases this unwanted excessive daytime sleepiness.

With OSAHS, daytime sleepiness may occur due to an interrupted night time sleep. MODAFINIL MYLAN only treats the symptom of sleepiness

and does not treat the cause of OSAHS. Whilst taking MODAFINIL MYLAN you should continue with treatments intended to help manage your underlying medical condition, such as Continuous Positive Airway Pressure, unless your doctor tells you otherwise.

If you have been diagnosed with moderate to severe chronic Shift Work Sleep Disorder (SWSD) and non-drug therapies have been unsuitable or unsuccessful, MODAFINIL MYLAN may be prescribed to keep you awake during your work shift.

Precisely how MODAFINIL MYLAN works is not known, but it is known that it acts on the central nervous system (the brain). It differs from other stimulant medicines that promote wakefulness. MODAFINIL MYLAN increases wakefulness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine for children under the age of 18 years and patients over 65 years.

This medicine is available only with a doctor's prescription.

Before you take MODAFINIL MYLAN

When you must not take it

Do not take MODAFINIL MYLAN if you have an allergy to:

- any medicine containing modafinil
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant, planning to become pregnant or likely to become pregnant.

Modafinil is suspected to cause birth defects if taken during pregnancy. You should ensure that you have reliable and effective methods of contraception.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a history of mental health problems
- heart problems, including, for example, angina (chest pain),

previous heart attack, enlarged heart

- an abnormal/irregular heart rhythm
- high blood pressure or your high blood pressure is controlled by medication
- kidney or liver problems

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Women of childbearing age require a negative pregnancy test the week prior to commencing treatment, as this medicine can harm the foetus.

It is not known whether modafinil passes into breastmilk and may affect your developing baby.

Do not take this medicine if you are under 18 or over 65 years old.

If you have not told your doctor about any of the above, tell them before you start taking MODAFINIL MYLAN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and MODAFINIL MYLAN may interfere with each other. These include:

- steroidal hormonal contraceptives, including the contraceptive pill, implants, injectables and hormone releasing intrauterine devices (IUDs)
- treatment for anxiety or muscle relaxant, such as diazepam (Valium)
- brain stimulants, such as methylphenidate (Ritalin)
- medicines to treat depression, including monoamine oxidase inhibitors (MAOIs), such as phenelzine (Nardil) and nialamide (Niamid)
- medicines to treat epilepsy or fits, such as phenytoin (Dilantin),

carbamazepine (Tegretol) and phenobarbitone (phenobarbital)

- medicines to treat fungal infections, such as ketoconazole and itraconazole
- medicines to help you sleep (sedatives), such as temazepam and triazolam
- rifampicin, an antibiotic used to treat tuberculosis
- ciclosporin, a medicine used to stop organ transplant rejection
- propranolol, a medicine used to treat high blood pressure, heart problems or migraine
- warfarin, a medicine used to prevent unwanted blood clotting
- theophylline, a medicine used to treat asthma and lung problems
- clomipramine in poor metabolisers (Anafranil)

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MODAFINIL MYLAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Each MODAFINIL MYLAN tablet contains 100mg of modafinil.

The usual daily dose of modafinil depends on individual response. For sleepiness associated with narcolepsy

or OSAHS, the dose ranges from 200mg to 400mg.

Each day you should take either:

- two MODAFINIL MYLAN tablets
- or
- up to four MODAFINIL MYLAN tablets.

For SWSD, a dose of 200mg is recommended.

Do not exceed the recommended daily dose unless directed to do so by your doctor.

How to take it

Swallow the tablets whole with a little water.

When to take it

For sleepiness associated with narcolepsy or OSAHS, you should take your MODAFINIL MYLAN tablets either:

- as two separate doses, one in the morning and one at midday,
- or
- as one dose, in the morning.

For narcolepsy or OSAHS, do not take your MODAFINIL MYLAN tablets later than midday, or you may have trouble sleeping at night.

For SWSD, you should take your MODAFINIL MYLAN tablets as a single dose 1 hour prior to commencing your shift work.

NOTE: Your doctor may start your treatment with less than two tablets a day.

If you need more than two tablets per day, your doctor should increase the dose stepwise, one additional tablet at a time, depending on how you respond to the treatment. The highest dose is four tablets per day.

If you are currently on another treatment for narcolepsy, your doctor will advise you how best to withdraw from that treatment and begin taking MODAFINIL MYLAN. Other stimulants used for narcolepsy may cause a "high" feeling. Be aware therefore that you may feel different

as you withdraw from other stimulants.

MODAFINIL MYLAN only treats the symptom of sleepiness. Other treatments intended to help manage your underlying medical condition should still be used regularly, unless your doctor tells you otherwise. You should commence or continue disease-modifying interventions (for example, Continuous Positive Airway Pressure).

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MODAFINIL MYLAN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking MODAFINIL MYLAN

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MODAFINIL MYLAN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, stop taking it and tell your doctor immediately.

Tell your doctor if you believe that MODAFINIL MYLAN is not helping your condition. Your doctor may need to change the dose.

If required, your doctor may monitor your blood pressure and perform an ECG before treatment.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take MODAFINIL MYLAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

MODAFINIL MYLAN may reduce the effectiveness of steroidal contraceptives. If you are using these forms of contraceptives while taking MODAFINIL MYLAN (and for 2 months after you stop treatment with MODAFINIL MYLAN) you should either use: an alternative birth control method or another effective birth control method together with your current contraceptive.

Be careful driving or operating machinery until you know how MODAFINIL MYLAN affects you.

This medicine may cause dizziness in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MODAFINIL MYLAN.

This medicine helps most people with excessive daytime sleepiness, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- nausea
- diarrhoea
- constipation
- dry mouth
- changes in taste
- mouth ulcers
- feeling thirsty
- poor appetite or weight loss

- runny nose
- chills
- sore throat
- nose bleed
- asthma
- anxious or nervous feeling
- dizziness
- back pain
- stiff neck, muscles
- muscle spasm, tremor, involuntary movements, muscle weakness or pain
- confusion or mood changes
- upset stomach
- trouble sleeping
- drowsiness, tiredness or fatigue
- high or low blood pressure
- tingling sensation in hands or feet (pins and needles)
- sweating
- acne
- herpes simplex
- changes in vision, lazy eye, or eye pain
- blood in the urine, cloudy urine or painful urination

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- mental (psychiatric) symptoms, including depression, anxiety, aggression, agitation, irritability, hallucinations, mania, thoughts of suicide or other mental problems
- chest pain or abnormal/fast heart beats or palpitations
- fits or convulsions

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, stop taking the tablets and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- yellowing of the skin or white of the eyes or dark urine
- fever, skin rash, hives (especially affecting the whole body) and itching
- sores in your mouth, or your skin blisters and peels
- sudden wheeziness, difficulty in breathing and swallowing
- shortness of breath, swelling of the legs
- cough, swelling of the face, lips, tongue, throat or other parts of the body

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking MODAFINIL MYLAN

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store MODAFINIL MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

MODAFINIL MYLAN tablets are white, round, biconvex, tablet.

Ingredients

MODAFINIL MYLAN contains 100 mg of modafinil as the active ingredient.

The tablets also contain the following inactive ingredients:

- lactose monohydrate
- maize starch
- croscarmellose sodium
- povidone
- magnesium stearate
- aluminium magnesium silicate
- purified talc

Each pack contains either 10, 30, 60 or 90 tablets.

Contains sugars (as lactose monohydrate). Contains sulfites.

Sponsor

Southern Cross Pharma Pty Ltd

Suite 5/118 Church Street
Hawthorn VIC 3122

Distributor

MODAFINIL MYLAN is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

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