

# MODAFINIL MYLAN

modafinil

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## 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 contains the active ingredient modafinil.

This medicine 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 MODAFINIL MYLAN has been prescribed for you.**

Your doctor may have prescribed MODAFINIL MYLAN for another reason.

## **Before you take MODAFINIL MYLAN**

### **When you must not take it**

#### **Do not take MODAFINIL MYLAN if you:**

- are allergic to any medicine containing modafinil
- any of the ingredients listed at the end of this leaflet
- are pregnant, or likely to become pregnant

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 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.**

Before you start taking MODAFINIL MYLAN you should discuss with your doctor any of the following points which apply to you:

- are under 18 or over 65 years old
- have a history of mental health problems
- have heart problems, including, for example, angina (chest pain), previous heart attack, enlarged heart
- have an abnormal/irregular heart rhythm
- have high blood pressure or your high blood pressure is controlled by medication
- have kidney or liver problems
- are taking hormonal contraceptives
- could become pregnant
- are currently receiving treatment for anxiety
- are breastfeeding

- are taking brain stimulants, such as methylphenidate
- are taking any medicines to treat depression, including those called monoamine oxidase inhibitors (MAOs)
- are taking medicines to treat epilepsy or fits, such as phenytoin, carbamazepine and phenobarbitone
- are taking medicines to treat fungal infections, such as ketoconazole and itraconazole
- are taking medicines to help you sleep (sedatives)
- are taking rifampicin, an antibiotic used to treat tuberculosis
- are taking cyclosporin, a medicine used to stop organ transplant rejection
- are taking propranolol, a medicine used to treat, for example, high blood pressure, heart problems or migraine
- are taking warfarin, a medicine used to prevent unwanted blood clotting
- are taking theophylline, a medicine used in asthma and lung problems

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

**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.**

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.

Your doctor will tell you how much you should take, when and how often.

### **How much to take**

Each MODAFINIL MYLAN tablet contains 100 mg of modafinil.

The usual daily dose of modafinil depends on individual response. For sleepiness associated with narcolepsy or OSAHS, the dose ranges from 200 mg to 400 mg.

Each day you should take either:

- two MODAFINIL MYLAN tablets

or

- up to four MODAFINIL MYLAN tablets

For SWSD, a dose of 200 mg 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).

**REMEMBER:** This medicine is only for you. Only a doctor can prescribe it for you. Never give it to anyone else. It may harm them, even if their symptoms appear to be the same as yours.

## **How long to take it**

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

## **If you forget to take it**

If you miss a dose of MODAFINIL MYLAN tablets, just take the next dose at your usual time.

**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 take too much (overdose)**

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) or go to the emergency department of your nearest hospital, if you think you or anyone else may have taken too much MODAFINIL MYLAN. Do this even if there are no signs of discomfort or poisoning.

## **While you are using MODAFINIL MYLAN**

### **Things you must do**

**If you are about to be started on any new medicine, tell 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.**

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

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

## **Things you must not do**

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

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

## **Things to be careful of**

MODAFINIL MYLAN may reduce the effectiveness of oral contraceptives. If you are using these forms of contraceptives while taking MODAFINIL MYLAN (and for 1 month 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.

## **Side effects**

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

MODAFINIL MYLAN may cause you to have a serious rash.

Stop MODAFINIL MYLAN and call your doctor right away or get emergency treatment if you have a skin rash, hives, sores in your mouth, or your skin blisters and peels, or if you have any sudden wheeziness, difficulty in breathing, swelling, rash or itching (especially affecting the whole body).

**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.**

MODAFINIL MYLAN may cause the following side effects in some people. In clinical studies, these side effects also occurred in people who received non-active (sugar) tablets. Tell your doctor if you notice any of the following:

- headache
- nausea
- diarrhoea
- dry mouth
- poor appetite
- runny nose
- sore throat
- nervous feeling
- dizziness

- back pain
- feeling anxious
- upset stomach
- trouble sleeping

Tell your doctor immediately if any of the following occur:

- skin rash, hives, sores in your mouth, or your skin blisters and peels
- swelling of your face, eyes, lips, tongue or throat
- trouble swallowing or breathing
- fever, shortness of breath, swelling of the legs, yellowing of the skin or white of the eyes or dark urine
- mental (psychiatric) symptoms, including depression, anxiety, aggression, agitation, irritability, hallucinations, mania, thoughts of suicide or other mental problems
- chest pain or abnormal heart beats
- fits or convulsions

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

# After using 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 as well.

Store MODAFINIL MYLAN tablets 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 and biconvex.

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

## **Ingredients**

Each MODAFINIL MYLAN tablet contains 100 mg of modafinil.

Each tablet also contains the following inactive ingredients:

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

## **Sponsor**

Southern Cross Pharma Pty Ltd

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Australian Registration number is AUST R 269913.

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