

MODAVIGIL®

Modafinil

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about MODAVIGIL tablets. As this leaflet does not contain all the available information, it is important that you talk to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving MODAVIGIL against the benefits this medicine is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What MODAVIGIL is used for

MODAVIGIL 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. MODAVIGIL decreases this unwanted excessive daytime sleepiness.

With OSAHS, daytime sleepiness may occur due to an interrupted night time sleep. MODAVIGIL only treats the symptom of sleepiness and does not treat the cause of OSAHS. Whilst taking MODAVIGIL 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, MODAVIGIL may be prescribed to keep you awake during your work shift.

Precisely how MODAVIGIL 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. MODAVIGIL increases wakefulness.

Your doctor may have prescribed MODAVIGIL for another reason. Ask your doctor if you have any questions about why MODAVIGIL has been prescribed for you.

Before you take MODAVIGIL

When you must not take it

You must not take MODAVIGIL if you:

- are allergic to modafinil or any of the other ingredients listed at the end of this leaflet. (See "MODAVIGIL tablets description"). Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue
- are pregnant currently, planning to become pregnant or likely to become pregnant or are breastfeeding.

If you could become pregnant, you should confirm by a pregnancy test that you are not pregnant within a week prior to starting treatment.

Modafinil is suspected to cause birth defects if taken during pregnancy.

Do not take MODAVIGIL if the packaging is torn or shows signs of tampering or the tablets do not look quite right.

Do not take MODAVIGIL if the expiry date on the pack has passed.

If you are not sure about whether you should start taking MODAVIGIL, you should contact your doctor.

Before you take it

Before you start taking MODAVIGIL you should discuss with your doctor any of the

following points which apply to you. If 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
- are pregnant, could become pregnant or are planning to 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 (MAOIs)
- 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

- are taking any other medicines, including any available without a prescription from your pharmacy, supermarket or health food shop

Tell your doctor about any of the above before you take MODAVIGIL. Your doctor will discuss the risks and benefits of using MODAVIGIL.

How to take MODAVIGIL

It is important that you take this medicine as directed by the doctor. Your doctor will tell you how much you should take, when and how often. Follow your doctor's instructions. If you are unsure ask your doctor or pharmacist.

How much should you take

Each MODAVIGIL 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 MODAVIGIL tablets
- or
- up to four MODAVIGIL tablets.

For SWSD, a dose of 200mg is recommended.

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

When and how should you take the tablets

For sleepiness associated with narcolepsy or OSAHS, you should take your MODAVIGIL 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 MODAVIGIL tablets later than midday, or you may have trouble sleeping at night.

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

Swallow the tablets whole with a little water.

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 MODAVIGIL. Other stimulants used for narcolepsy may cause a "high" feeling. Be aware therefore that you may feel different as you withdraw from other stimulants.

MODAVIGIL 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.

If you forget to take it

If you miss a dose of MODAVIGIL tablets, just take the next dose at

your usual time. Do not take an extra dose to "catch up".

While you are taking MODAVIGIL

Things you must do

If you could become pregnant, you should confirm by a pregnancy test that you are not pregnant within a week prior to starting treatment.

Tell your doctor if you are planning to become pregnant.

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MODAVIGIL.

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

Things you must not do

Do not give MODAVIGIL to anyone else, even if they have the same symptoms as you.

Things to be careful of

MODAVIGIL may reduce the effectiveness of hormonal contraceptives (including the contraceptive pill, implants, injectables and some intrauterine devices (IUDs)).

If you are using hormonal contraception, you should use an alternative non-hormonal method of birth control together with your current contraceptive whilst taking MODAVIGIL and for 2 months after you stop treatment with MODAVIGIL.

Do not drive or operate machinery until you know how MODAVIGIL affects you.

Side Effects

MODAVIGIL may cause you to have a serious rash.

Stop MODAVIGIL 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).

MODAVIGIL 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 these:

- 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 patients. Tell your doctor if you notice anything that makes you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Overdosage

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 MODAVIGIL. Do this, even if there are no signs of discomfort or poisoning.

MODAVIGIL tablets description

Each MODAVIGIL tablet contains 100mg of modafinil.

Each tablet also contains the following inactive ingredients:

- lactose
- starch- pre-gelatinised maize
- microcrystalline cellulose
- sodium croscarmellose
- povidone

- magnesium stearate.

MODAVIGIL tablets are white, capsule-shaped, debossed with "100" on one side.

Each pack contains either 10, 30 or 60 tablets.

Storage

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

Store MODAVIGIL tablets below 25°C. Keep the pack in a cool, dry place and away from direct heat and sunlight.

Do not store MODAVIGIL tablets in the bathroom or near a sink.

Keep MODAVIGIL tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

The Australian Registration Number is AUST R 168497.

This is not all the information available on MODAVIGIL. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

MODAVIGIL is supplied in Australia by:

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Australia
1800 288 382
www.tevapharma.com.au

and in New Zealand by:

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