MODAFINIL SANDOZ

Consumer Medicine Information (CMI) Summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MODAFINIL SANDOZ?

MODAFINIL SANDOZ contains the active ingredient modafinil. MODAFINIL SANDOZ is used to improve wakefulness in people with excessive sleepiness associated with the medical condition known as narcolepsy or with Obstructive Sleep Apnoea/ Hypopnoea Syndrome (OSAHS), or Shift Work Sleep Disorder (SWSD).

For more information, see Section 1. Why am I using MODAFINIL SANDOZ? in the full CMI.

2. What should I know before I use MODAFINIL SANDOZ?

Do not use if you have ever had an allergic reaction to modafinil or any of the ingredients listed at the end of the CMI.

Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use MODAFINIL SANDOZ? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MODAFINIL SANDOZ and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use MODAFINIL SANDOZ?

- The usual daily dose of MODAFINIL SANDOZ depends on individual response.
- Use as directed by your doctor.

More instructions can be found in Section 4. How do I use MODAFINIL SANDOZ? in the full CMI.

5. What should I know while using MODAFINIL SANDOZ?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using MODAFINIL SANDOZ. • Confirm by a pregnancy test that you are not pregnant within a week prior to starting treatment.
Things you should not do	• Do not stop using this medicine suddenly. • Do not give MODAFINIL SANDOZ to anyone else, even if they have the same symptoms as you.
Driving or using machines	• Do not drive or operate machinery until you know how MODAFINIL SANDOZ affects you.
Looking after your medicine	• Store below 25°C. • Keep in a cool, dry place and away from direct heat and sunlight.

For more information, see Section 5. What should I know while using MODAFINIL SANDOZ? in the full CMI.

6. Are there any side effects?

MODAFINIL SANDOZ can cause a serious rash. Stop taking, call your doctor, or get emergency treatment if you have skin rash, hives, sores in your mouth, or your skin blisters and peels, or if you have sudden wheeziness, difficulty breathing, swelling, rash, or itching (especially the whole body).

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

MODAFINIL SANDOZ

Active ingredient(s): *modafinil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MODAFINIL SANDOZ. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MODAFINIL SANDOZ.**

Where to find information in this leaflet:

1. Why am I using MODAFINIL SANDOZ?
2. What should I know before I use MODAFINIL SANDOZ?
3. What if I am taking other medicines?
4. How do I use MODAFINIL SANDOZ?
5. What should I know while using MODAFINIL SANDOZ?
6. Are there any side effects?
7. Product details

1. Why am I using MODAFINIL SANDOZ?

MODAFINIL SANDOZ contains the active ingredient modafinil.

MODAFINIL SANDOZ 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 SANDOZ decreases this unwanted excessive daytime sleepiness.

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

Precisely how MODAFINIL SANDOZ 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 SANDOZ increases wakefulness. Unlike other stimulants it does not overstimulate or produce a “high” feeling.

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

2. What should I know before I use MODAFINIL SANDOZ?

Warnings

Do not use MODAFINIL SANDOZ if:

- you are allergic to modafinil or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can use this medicine.
- you are pregnant currently, planning to become pregnant or likely to become pregnant or are breastfeeding.

Check with your doctor or pharmacist 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 currently receiving treatment for anxiety are taking hormonal contraceptives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with MODAFINIL SANDOZ and affect how it works. These include:

- brain stimulants, such as methylphenidate
- any medicines to treat depression, including those called monoamine oxidase inhibitors (MAOIs)

- medicines to treat epilepsy or fits, such as phenytoin, carbamazepine and phenobarbital
- medicines to treat fungal infections, such as ketoconazole and itraconazole
- medicines to help you sleep (sedatives)
- 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 in asthma and lung problems
- ioflupane, used for diagnostic imaging (e.g. DaTSCAN)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MODAFINIL SANDOZ.

4. How do I use MODAFINIL SANDOZ?

How much to take MODAFINIL SANDOZ

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 can take either
    - two MODAFINIL SANDOZ tablets; OR
    - up to four MODAFINIL SANDOZ tablets
- For SWSD, a dose of 200 mg is recommended.

Follow the instructions provided and use MODAFINIL SANDOZ until your doctor tells you to stop.

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

When to take MODAFINIL SANDOZ

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

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

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

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

How to take MODAFINIL SANDOZ

- Swallow the tablet 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 MODAFINIL SANDOZ. 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 SANDOZ 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 use MODAFINIL SANDOZ

MODAFINIL SANDOZ should be used regularly at the same time each day.

If you miss your dose, just take the next dose at your usual time.

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

If you use too much MODAFINIL SANDOZ

If you think that you have used too much MODAFINIL SANDOZ, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MODAFINIL SANDOZ?

Things you should 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 MODAFINIL SANDOZ, 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 MODAFINIL SANDOZ.

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

Call your doctor straight away if you:

- Have any serious side effects listed in Section 6.

Remind any doctor, dentist or pharmacist [add other health professionals as appropriate] you visit that you are using MODAFINIL SANDOZ.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not give MODAFINIL SANDOZ to anyone else, even if they gave the same symptoms as you.

Things to be careful of

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

If you are using these forms of contraceptives, you should either use an alternative non-hormonal birth control method together with your current contraceptive while taking MODAFINIL SANDOZ and for 2 months after you stop treatment with MODAFINIL SANDOZ.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MODAFINIL SANDOZ affects you.

MODAFINIL SANDOZ may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store MODAFINIL SANDOZ tablets below 25°C.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

Less serious side effects

Less serious side effects	What to do
Body as a whole: • headache • runny nose • sore throat • back pain **Digestive system:** • nausea • diarrhoea • dry mouth • poor appetite • upset stomach **Nervous system:** • nervous feeling • dizziness • feeling anxious • trouble sleeping	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Other serious side effects: • 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 **MODAFINIL SANDOZ may cause a serious rash:** • 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.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MODAFINIL SANDOZ contains

Active ingredient (main ingredient)	Modafinil
Other ingredients (inactive ingredients)	Lactose monohydrate Maize starch Croscarmellose sodium Povidone Magnesium stearate Aluminium magnesium silicate Purified talc
Potential allergens	Sugars (as lactose) Sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What MODAFINIL SANDOZ looks like

MODAFINIL SANDOZ is white, round, biconvex tablet (AUST R 269914).

Who distributes MODAFINIL SANDOZ

Sandoz Pty Ltd

100 Pacific Highway

North Sydney

NSW 2060

Australia

Tel: 1800 726 369

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