MODAFINIL VIATRIS

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 VIATRIS?

MODAFINIL VIATRIS contains the active ingredient modafinil. MODAFINIL VIATRIS 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 VIATRIS? in the full CMI.

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

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 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 VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MODAFINIL VIATRIS 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 VIATRIS?

- 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

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

5. What should I know while using MODAFINIL VIATRIS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using MODAFINIL VIATRIS. • If you could become pregnant, you should confirm by a pregnancy test that you are not pregnant within a week prior to starting treatment. • If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking MODAFINIL VIATRIS. • If you become pregnant while you are taking MODAFINIL VIATRIS, stop taking it and tell your doctor immediately
Things you should not do	• Do not give MODAFINIL VIATRIS 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 VIATRIS 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 VIATRIS? in the full CMI.

6. Are there any side effects?

MODAFINIL VIATRIS 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 VIATRIS

Active ingredient(s): *[modafinil]*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MODAFINIL VIATRIS. **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 VIATRIS.**

Where to find information in this leaflet:

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

1. Why am I using MODAFINIL VIATRIS?

MODAFINIL VIATRIS contains the active ingredient modafinil.

MODAFINIL VIATRIS 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 VIATRIS decreases this unwanted excessive daytime sleepiness.

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

Precisely how MODAFINIL VIATRIS 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 VIATRIS increases wakefulness.

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

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

Warnings

Do not use MODAFINIL VIATRIS 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.

Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.

- you are pregnant currently, planning to become pregnant or likely to become pregnant or are breastfeeding.

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

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

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

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- 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 ciclosporin, 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 MODAFINIL VIATRIS. Your doctor will discuss the risks and benefits of using MODAFINIL VIATRIS.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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 VIATRIS.

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

- brain stimulants, such as methylphenidate
- 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)

4. How do I use MODAFINIL VIATRIS?

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 to take

- Each MODAFINIL VIATRIS 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 200 mg to 400 mg.
  Each day you should take either:
  - o two MODAFINIL VIATRIS tablets
    or
  - o up to four MODAFINIL VIATRIS 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.
- Follow the instructions provided and use MODAFINIL VIATRIS until your doctor tells you to stop.

When to take MODAFINIL VIATRIS

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

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

How to take MODAFINIL VIATRIS

- swallow tablet 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 MODAFINIL VIATRIS. 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 VIATRIS 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 VIATRIS

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

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

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

If you use too much MODAFINIL VIATRIS

If you think that you have used too much MODAFINIL VIATRIS, 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 VIATRIS?

Things you should do

- Tell your doctor if you are planning to become pregnant.
- Tell your doctor if you are planning to become pregnant.
- If you become pregnant while you are taking MODAFINIL VIATRIS, stop taking it and tell your doctor immediately.
- Tell your doctor if you believe that MODAFINIL VIATRIS is not helping your condition. Your doctor may need to change the dose.

Remind any doctor, dentist or pharmacist you visit that you are using MODAFINIL VIATRIS.

Call your doctor straight away if you:

- Have any serious side effects listed in Section 6

Things you should not do

- Do not give MODAFINIL VIATRIS to anyone else, even if they have the same symptoms as you. MODAFINIL VIATRIS may reduce the effectiveness of hormonal contraceptives (including the contraceptive pill, implants, injectables and some intrauterine devices (IUDs)).

Things to be careful of

- MODAFINIL VIATRIS 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 birth control together with your current contraceptive whilst taking MODAFINIL VIATRIS and for 2 months after you stop treatment with MODAFINIL VIATRIS.

Driving or using machines

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

MODAFINIL VIATRIS may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep MODAFINIL VIATRIS tablets in the original pack until it is time to take them.
- Store MODAFINIL VIATRIS tablets below 25°C. Keep the pack in a cool, dry place and away from direct heat and sunlight.

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

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 about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal: • dry mouth • diarrhoea • upset stomach **Metabolism:** • poor appetite • nausea **Respiratory:** • runny nose • sore throat **Nervous system** • headache • dizziness • feeling anxious • trouble sleeping • nervous feeling **Musculoskeletal** • back pain	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **In clinical studies, these side effects also occurred in people who received non-active (sugar) tablets.**

Serious side effects

Serious side effects	What to do
Skin disorders: • skin rash, hives, sores in your mouth, or your skin blisters and peels **General disorders:** • 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 **Nervous system:** • fits or convulsions **Heart related:** • chest pain or abnormal heart beats	**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.** **MODAFINIL VIATRIS may cause you to have a serious rash.** **Stop MODAFINIL VIATRIS 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).**

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 VIATRIS contains

Active ingredient (main ingredient)	Modafinil 100 mg
Other ingredients (inactive ingredients)	Lactose monohydrate Microcrystalline cellulose Mannitol Crospovidone Povidone Magnesium stearate
Potential allergens	Sugars as lactose

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

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

What MODAFINIL VIATRIS looks like

MODAFINIL VIATRIS tablets are white to off-white, capsule shape, biconvex, uncoated tablets with 'L233' debossed on one side and plain on the other side (AUST R 395231).

MODAFINIL VIATRIS 100 mg tablets are available in packs of 30 and 60 tablets.

Not all presentations are available.

Who distributes MODAFINIL VIATRIS

Sponsor

Helix Pharmaceuticals Pty Ltd

C/-EGA Corporate Advisers Pty Ltd

Level 12, 468 St Kilda Rd

Melbourne VIC 3004

Contact: info@helixpharmaceuticals.com.au

Distributor

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

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Millers Point NSW 2000

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