NUVIGIL®

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 NUVIGIL?

NUVIGIL contains the active ingredient armodafinil. NUVIGIL is used to improve wakefulness in people with excessive daytime sleepiness associated with the medical condition known as narcolepsy or with Obstructive Sleep Apnoea/HypopnoeaSyndrome (OSAHS), or shift work sleep disorder (SWSD).

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

2. What should I know before I use NUVIGIL?

Do not use if you have ever had an allergic reaction to armodafinil 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 NUVIGIL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NUVIGIL 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 NUVIGIL?

- 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 NUVIGIL? in the full CMI.

5. What should I know while using NUVIGIL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using NUVIGIL. • 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 NUVIGIL. • If you become pregnant while you are taking NUVIGIL, stop taking it and tell your doctor immediately.
Things you should not do	• Do not give NUVIGIL 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 NUVIGIL affects you.
Looking after your medicine	• Store below 25°C. • Keep the packaging in a cool, dry place and away from direct heat and sunlight.

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

6. Are there any side effects?

Stop NUVIGIL 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).

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.

NUVIGIL®

Active ingredient(s): *Armodafinil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NUVIGIL. **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 NUVIGIL.**

Where to find information in this leaflet:

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

1. Why am I using NUVIGIL?

NUVIGIL contains the active ingredient armodafinil.

NUVIGIL 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. NUVIGIL decreases this unwanted excessive daytime sleepiness.

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

Precisely how NUVIGIL 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. NUVIGIL increases wakefulness.

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

2. What should I know before I use NUVIGIL?

Warnings

Do not use NUVIGIL if:

- you are allergic to armodafinil, modafinil or any of the other ingredients listed at the end of this leaflet. Signs of allergic reaction may include a skin rash, itching, shortness of breath or swelling of the face, lips or tongue.
  Always check the ingredients to make sure you can use this medicine.
- are pregnant currently, planning to become pregnant or likely to become pregnant or are breastfeeding.

Do not take NUVIGIL if the packaging shows signs of tampering or the tablets do not look quite right.
Do not take NUVIGIL if the expiry date on the packaging has passed.
If you are not sure about whether you should start taking NUVIGIL, you should contact your doctor.

Check with your doctor 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, oxcarbamazepine, 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 antibiotics such as rifampicin or erythromycin, clarithromycin
- are taking cyclosporine, 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 quetiapine, a medicine used to treat mental health conditions such as schizophrenia or bipolar disorder
- are taking omeprazole or esomeprazole, medicines used to treat stomach ulcers or gastric reflux
- 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 NUVIGIL. Your doctor will discuss the risks and benefits of using NUVIGIL.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor 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.

Armodafinil 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 NUVIGIL 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, oxcarbamazepine, carbamazepine and phenobarbitone
- medicines to treat fungal infections, such as ketoconazole and itraconazole
- medicines to help you sleep (sedatives)
- antibiotics such as rifampicin or erythromycin, clarithromycin
- cyclosporine, a medicine used to stop organ transplant rejection
- propranolol, a medicine used to treat, for example, 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
- quetiapine, a medicine used to treat mental health conditions such as schizophrenia or bipolar disorder
- omeprazole or esomeprazole, medicines used to treat stomach ulcers or gastric reflux
- ioflupane, used for 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 NUVIGIL.

4. How do I use NUVIGIL?

How much to take

- Follow the instructions provided and use NUVIGIL until your doctor tells you to stop.
- Each NUVIGIL tablet contains 50mg, 150mg or 250mg of armodafinil.
- The usual daily dose of armodafinil depends on individual response. For sleepiness associated with narcolepsy or OSAHS, the dose ranges from 150mg to 250mg.
- For SWSD, a dose of 150mg is recommended.
- Do not exceed the recommended daily dose unless directed to do so by your doctor.

When to take NUVIGIL

- NUVIGIL tablet should be used as one dose, in the morning, for sleepiness associated with narcolepsy or OSAHS.
- For narcolepsy or OSAHS, do not take your NUVIGIL tablet later than midday, or you may have trouble sleeping at night.
- For SWSD, you should take your NUVIGIL tablet as a single dose 1 hour prior to commencing your shift work.

How to take NUVIGIL

- **Swallow the tablet whole with a little water.**
- **Take your dose before food as food can slow down the rate at which the treatment enters your blood stream and may delay the effects of your medication.**

If you are currently on another treatment for narcolepsy, your doctor will advise you how best to withdraw from that treatment and begin taking NUVIGIL. Other stimulants used for narcolepsy may cause a "high" feeling. Be aware therefore that you may feel different as you withdraw from other stimulants. NUVIGIL is not associated with this "high" feeling. It works on excessive daytime sleepiness.

NUVIGIL 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 NUVIGIL

NUVIGIL should be used regularly at the same time each day.

If you miss your dose 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 NUVIGIL

If you think that you have used too much NUVIGIL, 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 NUVIGIL?

Things you should do

- Tell your doctor if you are planning to become pregnant.
- 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 could become pregnant, you should also use effective contraception during therapy with NUVIGIL and for one month after discontinuation of NUVIGIL treatment.
- If you become pregnant while you are taking NUVIGIL, 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 NUVIGIL.
- Tell your doctor if you believe that NUVIGIL 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 you visit that you are using NUVIGIL.

Things you should not do

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

Things to be careful of

- NUVIGIL 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 NUVIGIL and for 2 months after you stop treatment with NUVIGIL.

Driving or using machines

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

NUVIGIL may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep NUVIGIL tablets in the original packaging until it is time to take them.
- Store NUVIGIL tablets below 25°C. Keep the packaging 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 • Vomitting **Metabolism** • Decreased 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. • Anorexia **Gastrointestinal** • upper abdominal pain • excessive urination **Nervous system** • Fits or convulsions	**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.** NUVIGIL may cause you to have a serious rash. **Stop taking NUVIGIL 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, or itching (especially affecting the whole body).**
Heart related • Chest pain or abnormal heart beats	

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 NUVIGIL contains

Active ingredient (main ingredient)	Each NUVIGIL tablet contains either 50mg, 150mg or 250mg of armodafinil.
Other ingredients (inactive ingredients)	• pregelatinised maize starch • microcrystalline cellulose • croscarmellose sodium • 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 NUVIGIL. If you have any more questions or are unsure about anything, ask your doctor or pharmacist.

What NUVIGIL looks like

NUVIGIL 50mg tablets are white to off-white, round, uncoated tablets debossed with "C" logo on one side and "205" on the other.

NUVIGIL 150mg tablets are white to off-white, oval, uncoated tablets debossed with "C" logo on one side and "215" on the other.

NUVIGIL 250mg tablets are white to off-white, oval, uncoated tablets debossed with "C" logo on one side and "225" on the other.

NUVIGIL is supplied in packs containing 7 or 30 tablets.

The Australian Registration Numbers are:

50mg tablet-blister

AUST R 272052

150 mg tablet - blister:

AUST R 226559

250 mg tablet - blister:

AUST R 226558

Who distributes NUVIGIL

NUVIGIL is sponsored in Australia by:

Neuraxpharm Australia Pty Ltd

Suite 3.12, 32 Delhi Road,

Macquarie Park, NSW 2113

Australia

1800 060 095

Email: medinfo-australia@neuraxpharm.com

www.neuraxpharm.com

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