Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

• If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

• If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What Modafinil is and what it is used for

The active ingredient in the tablets is modafinil.

Modafinil can be taken by adults who suffer from excessive daytime sleepiness to help them to stay awake.

Narcolepsy is a condition that causes excessive daytime sleepiness and a sudden loss of muscle tone (known as ‘sleep attacks’ in inappropriate situations (sleep attacks). Modafinil may improve your narcolepsy and reduce the likelihood that you will have sleep attacks but there may still be other changes in your condition and your doctor will advise you.

2. What you need to know before you take Modafinil

Do not take Modafinil:

• if you are allergic to modafinil, or to any of the other ingredients of this medicinal product (listed in section 6).
• if you have an irregular heartbeat.
• if you have uncontrolled, moderate to severe high blood pressure (hypertension).

Warnings and precautions:

talk to your doctor or pharmacist before taking Modafinil:

• if you have heart problems or high blood pressure. Your doctor will need to check those regularly while you are taking Modafinil.
• if you have ever had depression, low mood, anxiety, psychosis (loss of contact with reality or mania (over-excitement or feeling of extreme happiness) or bipolar disorder because this can make your condition worse.
• if you have liver problems (because you will need to take a lower dose).
• if you have had alcohol or drug problems in the past.

Children and adolescents

Children aged 18 years and younger should not take this medicine.

Other things to talk to your doctor or pharmacist about

Some people have reported having suicidal or aggressive thoughts or behaviors while taking this medicine.

Tell your doctor straight away if you or anyone else is becoming depressed, feel aggressive or hostile towards other people or have suicidal thoughts or other changes in your behaviour (see section 4).

This medicine has the potential for you to become reliant (dependent) on it after longterm use.

If you need to take it for a long time your doctor will check regularly that it is still the best medicine for you.

Other medicines and Modafinil

Tell your doctor or pharmacist if you are taking, have taken, or might take any other medicines.

Modafinil and certain other medicines can affect each other and your doctor may need to adjust the doses that you are taking. It is especially important to tell your doctor the following medicines as well as Modafinil:

• Statin medicines for lowering cholesterol (because the co-reactive pill, imprints, intravenous (“IV”) injections).

You will need to consider other birth control methods while taking Modafinil, and for two months after stopping treatment, because Modafinil reduces their effectiveness.

• Omeprazole (for acid reflux, indigestion or ulcers).

• Antiviral medicines to treat HIV infection (protease inhibitors e.g. indinavir or ritonavir).

• Ciclosporin (to prevent organ transplant rejection, or for arthritis or psoriasis).

Medicines for epilepsy (e.g. carbamazepine, phenobarbital or phenytoin).

Medicines for depression (e.g. amitriptyline, citalopram or fluoxetine) or anxiety (e.g. diazepam).

• Medicines for thinning the blood (e.g. warfarin).

Your doctor will monitor your blood clotting times during treatment.

• Calcium channel blockers or beta- blockers for high blood pressure or heart problems (e.g. amlodipine, verapamil or propranolol).

• Statin medicines for lowering cholesterol (e.g. atorvastatin or simvastatin).

Pregnancy and breast-feeding

If you think you may be pregnant, or are planning to become pregnant, or are breast-feeding, you should not take Modafinil.

Modafinil is suspected to cause birth defects in mice. In some cases (but it may be), are planning to become pregnant, or are planning to breast-feed, you should not take Modafinil.

Talk to your doctor about the birth control methods that will be right for you while you are taking Modafinil (and for two months after stopping) or if you have any other concerns.

Driving and using machines

Modafinil may cause blurred vision or dizziness in 1 in 10 people. If you are affected or you find that while using this medication you still feel very sleepy, do not attempt to drive or operate machines.

Modafinil tablet contains lactose. If you have been told by your doctor that you have an intolerance to some sugars you have been told by your doctor that you have been told by your doctor that you have been told by your doctor that you have an intolerance to some sugars you have been told by your doctor that you have an intolerance to some sugars you have been told by your doctor that you have an intolerance to some sugars you have been told by your doctor that you have an intolerance to some sugars.

3. How to take Modafinil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Tablets should be swallowed whole with water.

Adults

The recommended dose is 200 mg a day. This can be divided into two doses (in the morning) or divided into two doses a day (100 mg in the morning and 100 mg at midday).

Your doctor in some cases may decide to increase your dose up to 400 mg a day. Elderly patients (over 65 years of age)

The usual dose is 100 mg a day.

your doctor will check regularly to make sure that it is right for you.

If you take more Modafinil than you should

If you take too many tablets you may feel sick, feel restless, have a fast heart beat, become confused, agitated, anxious or excited.

You may also feel drowsy, feel sleepy, have a change in the speed of your heart beat or an increase in blood pressure.
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor straight away if:

- You have suddenly difficulty breathing or wheezing or your face, mouth or throat begins to swell.
- You notice a skin rash or itching (especially if it affects your whole body). Severe rashes may cause blistering or peeling of the skin, ulcers in your mouth, eyes, nose or genitals. You may also have a high temperature (fever) and abnormal blood test results.
- You feel any change in your mental health and wellbeing. The signs may include:
  - mood swings or abnormal thinking,
  - aggression or hostility,
  - difficulty in concentrating or making decisions,
  - feelings of extreme happiness or excitement,
  - anxiety or nervousness,
  - depression, suicidal thoughts or behaviors
  - abnormal (unusual) agitation or psychosis (a loss of contact with reality which may include delusions or see things that are not real), feeling detached from reality or personality disorder.

Other side effects include the following:

Very common (may affect more than 1 in 10 people):
- Headache.
- Common (may affect up to 1 in 10 people):
  - Dizziness.
  - Sleeplessness, extreme tiredness or difficulty sleeping (insomnia).
  - Aching or swelling of your heart beat, which may be faster than normal.
  - Flushing.
  - Difficulty swallowing.
  - Loss of appetite, feeling sick, stomach pain, indigestion, diarrhoea or constipation.
  - Weakness.
  - Numbness or tingling of the hands or feet (‘pins and needles’).
  - Blurred vision.
- Abnormal blood test results showing no serious harm (increased liver enzymes).
- Irritability

Uncommon (may affect up to 1 in 100 people):
- Back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching or tremor.
- Changes in your heart rate.
- Difficulty moving muscles or other movement problems, muscle tension, coordination problems.
- Headache symptoms including titchy runny nose or watery eyes.
- Increased cough, asthma or shortness of breath.
- Skin rash, itch or sticky skin.
- Changes in blood pressure (high or low), chest tightness (angina), coughing or irregular or unusually slow heart beat.
- Difficulty swallowing, swollen tongue or muscles.
- Excess wind, reflux (bring back fluid from the stomach), increased appetite, weight changes, thirst or other symptoms of diabetes.
- Being sick (vomiting)
- Migraine.
- Speech problems with increased blood sugar:
  - High blood cholesterol.
  - Swollen hands and feet.
- Disrupted sleep or abnormal dreams,
- Loss of sex drive.
- Nose bleed, sore throat or inflamed nasal passages (sinusitis).
- Abnormal urination.
- Abnormal urine or more frequent urination.
- Abnormal periods.
- Abnormal urination results showing that the numbers of your white blood cells have changed.
- Restlessness with increased body movement.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowscard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Modafinil

Keep this medicine out of the sight and reach of children.

Use within 4 months after first opening the HDPE bottle. This medicine does not require any special storage conditions. Do not use this medicine after the expiry date which is stated on the label, container and blister after EXPIRY. The expiry date refers to the last date of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer need. These measures will help protect the environment.

6. Contents of the pack and other information

What Modafinil contains
- The active substance is modafinil.

Each tablet contains 200 mg of modafinil.

- The other ingredients are lactose monohydrate, sodium starch, povidone (k-30), magnesium stearate.

What Modafinil looks like and the contents of the pack

This medicinal product is presented as a Tablet

Modafinil 100 mg Tablets:
- White to off-white, capsule shaped, uncoated tablets, debossed with ‘41’ on one side and ‘J’ on the other side.

Modafinil 200 mg Tablets:
- White to off-white, capsule shaped, uncoated tablets, debossed with ‘4’ & ‘2’ separated by line score on one side on ‘F’ on the other side.

This tablet can be divided into equal doses.

This medicinal product is available in PVC/PVDC aluminium foil blister packs. Each blister pack contains 100 mg of modafinil.

- The active substance is modafinil.
- The Other ingredients are lactose monohydrate, sodium starch, povidone (k-30), magnesium stearate.

This leaflet was last revised in 06/2019.