

PACKAGE LEAFLET: INFORMATION FOR THE USER

Modafinil 200mg Tablets

(Modafinil)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Modafinil Tablets are and what they are used for
2. Before you take Modafinil Tablets
3. How to take Modafinil Tablets
4. Possible side-effects
5. How to store Modafinil Tablets
6. Further information

1. WHAT MODAFINIL TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in the tablets is modafinil. This product will be referred to as Modafinil Tablets throughout this leaflet. Modafinil Tablets can be taken by adults who suffer from narcolepsy to help them to stay awake. Narcolepsy is a condition that causes excessive daytime sleepiness and a tendency to fall asleep suddenly in inappropriate situations (sleep attacks). Modafinil Tablets may improve your narcolepsy and reduce the likelihood that you will have sleep attacks but there may still be other ways that you can improve your condition and your doctor will advise you.

2. BEFORE YOU TAKE MODAFINIL TABLETS

Do not take Modafinil Tablets if you:

- Are **allergic** (hypersensitive) to modafinil or to any of the other ingredients of Modafinil Tablets (see section 6 'What Modafinil Tablets contain')
- Have an **irregular heartbeat**
- Have **uncontrolled, moderate to severe high blood pressure** (hypertension).

Take special care with Modafinil Tablets if you:

- Have any **heart problems** or **high blood pressure**. Your doctor will need to check these regularly while you are taking Modafinil Tablets
- 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 Modafinil Tablets may make your condition worse
- Have **kidney or liver problems** (because you will need to take a lower dose)
- Have had **alcohol** or **drug problems** in the past.

Children aged less than 18 years 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 **behaviour** while taking this medicine. **Tell your doctor straight away** if you notice that you are becoming **depressed, feel aggressive or hostile** towards other people or have **suicidal thoughts** or other changes in your behaviour (see section 4). You may want to consider asking a family member or close friend to help you look out for signs of depression or other changes in your behaviour.
- This medicine has the potential for you to become reliant (dependent) on it after long-term 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Modafinil Tablets 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 if you are taking any of the following medicines as well as Modafinil Tablets:

- Hormonal **contraceptives** (including the contraceptive pills, implants, intrauterine devices (IUDs) and patches). You will need to consider other birth control methods while taking Modafinil Tablets, and for two months after stopping treatment, because Modafinil Tablets reduce their effectiveness.
- **Omeprazole** (for acid reflux, indigestion or ulcers).
- Antiviral medicines to treat HIV infection (protease inhibitors e.g. indinavir or ritonavir).
- **Ciclosporin** (used 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 are pregnant (or think that you may be), are planning to become pregnant, or are breast-feeding, you should not take Modafinil Tablets. Modafinil is suspected to cause birth defects if taken during pregnancy.

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

Driving and using machines

Modafinil Tablets can cause blurred vision or dizziness in up to 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 machinery.

Important information about some of the ingredients of Modafinil Tablets:

Modafinil Tablets contains **lactose**.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE MODAFINIL TABLETS

Always take Modafinil Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Tablets should be swallowed whole with water.

Adults

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

Your doctor in some cases may decide to increase your daily dose up to 400mg.

Elderly patients (over 65 years of age)

The usual dose is 100mg a day.

Your doctor will only increase your dose (up to the maximum 400mg a day) provided that you do not have any liver or kidney problems.

Adults with severe kidney and liver problems

The usual dose is 100mg a day.

Your doctor will review your treatment regularly to check that it is right for you.

If you take more Modafinil Tablets than you should

If you take too many tablets you may feel sick, restless, disorientated, confused, agitated, anxious or excited. You may also have difficulty sleeping, diarrhoea, hallucinations (sensing things that are not real), chest pain, a change in the speed of your heartbeat or an increase in blood pressure.

Please read the back of this leaflet.



GENUS PHARMACEUTICALS

Contact your nearest hospital casualty department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining tablets with you.

If you forget to take Modafinil Tablets

If you forget to take your medicine take the next dose at the usual time, do not take a double dose to make up for the forgotten one.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Modafinil Tablets can cause side-effects, although not everybody gets them.

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

- you have sudden difficulty breathing or wheeziness 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
 - forgetfulness or confusion
 - feeling of extreme happiness
 - over-excitement or hyperactivity
 - anxiety or nervousness
 - depression, suicidal thoughts or behaviour
 - agitation or psychosis (a loss of contact with reality which may include delusions or sensing things that are not real), feeling detached or numb, or personality disorder.

Other side-effects include the following:

Very common side-effects (may affect up to 1 in 10 people):

- Headache.

Common side-effects (may affect up to 1 in 10 people):

- Dizziness
- Sleepiness, extreme tiredness or difficulty sleeping (insomnia)
- Awareness of your heartbeat, which may be faster than normal
- Chest pain
- Flushing
- Dry mouth
- 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 how your liver is working (increased liver enzymes)
- Irritability.

Uncommon side-effects (may affect up to 1 in 100 people):

- Back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching or tremor
- Vertigo (spinning sensation)
- Difficulty moving muscles smoothly or other movement problems, muscle tension, coordination problems
- Hayfever symptoms including itchy/runny nose or watery eyes
- Increased cough, asthma or shortness of breath
- Skin rash, acne or itchy skin
- Sweating
- Changes in blood pressure (high or low), abnormal heart trace (ECG), and irregular or unusually slow heartbeat
- Difficulty swallowing, swollen tongue or mouth ulcers
- Excess wind, reflux (bringing back fluid from the stomach), increased appetite, weight changes, thirst or taste alteration
- Being sick (vomiting)
- Migraine
- Speech problems
- Diabetes 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 vision or dry eyes
- Abnormal urine or more frequent urination
- Abnormal periods
- Abnormal blood test 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, pharmacist or nurse. 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/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MODAFINIL TABLETS

Keep out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the blister strip and the outer pack after 'Exp'. The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions. Please store this product in the outer carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Modafinil 200mg Tablets contain:

The active substance is modafinil. Each tablet contains 200mg modafinil.

The other ingredients are: Crospovidone (Type A), Crospovidone (Type B), Starch (maize) Pregelatinised, Cellulose Microcrystalline, Povidone K-90, Povidone K-30, Lactose Monohydrate, Silica colloidal anhydrous, Talc, Magnesium Stearate.

What Modafinil 200mg Tablets look like and contents of the pack

Modafinil Tablets are white to off white coloured capsule shaped tablets debossed with "M" on one side and "200 MG" on the other side with a breakline between 200 and MG.

The tablet can be divided into equal halves.

These tablets are available in PVC/Aclar-Aluminium and OPA/Aluminium/PVC-Aluminium blisters.

Packed in blister packs of 10 or 30. Not all pack sizes may be marketed.

POM

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Modafinil 200mg Tablets

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