

## Package leaflet: Information for the patient

### Modafinil 100 mg Tablets modafinil

**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.
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#### **What is in this leaflet**

1. What Modafinil is and what it is used for
2. What you need to know before you take Modafinil
3. How to take Modafinil
4. Possible side effects
5. How to store Modafinil
6. Contents of the pack and other information

#### **1. What Modafinil is and what it is used for**

Modafinil tablets contain the active substance modafinil, which belongs to a group of medicines known as psychoanaleptic.

Modafinil 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 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. What you need to know before you take Modafinil**

##### **Do not take Modafinil :**

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

#### **Warning and precautions**

Talk to your doctor or pharmacist before taking Modafinil if you:

- Have or have ever had any **heart problems** or **high blood pressure**. Your doctor will need to check these regularly while you are taking modafinil.
- Have ever had **depression, low mood, severe anxiety, psychosis** (loss of contact with reality), agitation or **mania** (over-excitement or feeling of extreme happiness), sleeplessness, hallucination (sensing things that are not there), delusions or **bipolar disorder** because modafinil may make your condition worse.
- Have severe **kidney** or **liver problems** (because you will need to take a lower dose).
- Have had **alcohol** or **drug problems** in the past.
- Are currently taking hormonal contraceptives to prevent pregnancy, as this medicine may reduce how well they work. Your doctor may advise you to use alternative method of contraception during treatment and for two months after stopping treatment with this medicine (see section 2, Other medicines and Modafinil).

### During treatment

Talk to your doctor or pharmacist:

- If you notice fever, rash, inflammation of the lining of heart which may be seen in tests, inflammation of liver or abnormal liver functioning which may be seen in blood tests, an increase or decrease in certain type of blood cells (which may cause symptoms such as an increase in infections or fever e.g. sore throat, mouth ulcers that you get or if you notice that you bruise or bleed more easily without explanation). These may be signs of multi-organ hypersensitivity reaction which may be life-threatening.
- If 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 (see section 4, Possible side effects).
- If you have difficulty falling and staying asleep.

### **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.

### **Children and adolescents**

Children and adolescents aged less than 18 years should not take this medicine.

### **Other medicines and Modafinil**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. 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 if you are taking any of the following medicines as well as modafinil:

- Hormonal **contraceptives** (including the contraceptive pill, implant, intrauterine devices (IUDs) and patches. 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 inhibitor 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, triazolam, midazolam or buspirone).
- Propranolol (used to treat high blood pressure).
- Medicines for thinning the blood (e.g. **warfarin**). Your doctor will monitor your blood clotting times during treatment.
- Calcium channel blockers for **high blood pressure** or heart problems (e.g. amlodipine, verapamil).
- Statin medicines for lowering **cholesterol** (e.g. atorvastatin or simvastatin).

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think that you may be pregnant, or are planning to have a baby, you should not take modafinil. It is not known if your medicine may harm your unborn baby.

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 containing medicinal products 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.

Modafinil contains **lactose**.

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

## **3. How to take Modafinil**

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

### Adults

The recommended dose is 200 mg a day. This can be taken once daily (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 daily dose up to 400 mg.

### Older people (over 65 years of age)

The recommended dose is 100 mg a day.

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

### Adults with severe liver problems

The recommended dose is 100 mg a day.

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

### Method of administration

Tablets should be swallowed whole with water.

### **If you take more Modafinil than you should**

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

Contact your nearest hospital casualty department or tell your doctor or pharmacist immediately as taking too many tablets may be life threatening. Take this leaflet and any remaining tablets with you.

### **If you forget to take Modafinil**

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 a forgotten dose.

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

## **4. Possible side effects**

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 any of the following side effects:**

- You have sudden signs of allergic reactions such as rash, itching or hives on the skin, difficulty breathing or wheeziness or your face, mouth or throat begins to swell, disorder of lymph node (signs may include painful, warm, red lumps under your skin, fever or unusual tiredness) .
- 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. (see section 2, Warnings and precautions).
- Diabetes with increased blood sugar (symptoms may include frequent urination, excessive thirst, unexplained weight loss, extreme hunger, sudden change in vision, tiredness).
- 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** (may affect more than 1 in 10 people):

- Headache

**Common** (may affect up to 1 in 10 people):

- Dizziness, feeling irritable
- Sleepiness, extreme tiredness or difficulty sleeping (insomnia)
- Awareness of your heart beat, 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).

**Uncommon** (may affect up to 1 in 100 people):

- Back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching or tremor.
- Reduced sensation.
- Vertigo (spinning sensation).
- Difficulty moving muscles smoothly or other movement problems, muscle twitching, 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 heart beat.
- 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.
- 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.

## **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/yellowcard](http://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**

Keep this medicine 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 that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. 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 100 mg modafinil

The other ingredients are: crospovidone (Type A), crospovidone (Type B), maize starch pregelatinised, cellulose microcrystalline, povidone K-90, povidone K-30, lactose monohydrate (see Section 2 “Modafinil contains lactose”), silica colloidal anhydrous, talc, and magnesium stearate.

### **What Modafinil looks like and contents of the pack**

Modafinil is white to off-white coloured capsule-shaped tablet debossed with “M” on one side and “100 MG” on the other side.

Modafinil is available in blister pack of 10, 30, 60 or 90.

Not all pack sizes may be marketed

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

### **Manufacturer**

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

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