Package leaflet: Information for the patient

PROVIGIL® 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PROVIGIL is and what it is used for

The active ingredient in the tablets is modafinil. 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 PROVIGIL

Do not take PROVIGIL
- 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).

Warnings and precautions

Talk to your doctor or pharmacist before taking PROVIGIL if you:
- Have any **heart problems** or **high blood pressure**. Your doctor will need to check these regularly while you are taking PROVIGIL.
- 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 PROVIGIL 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.

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 aged less than 18 years should not take this medicine.

Other medicines and PROVIGIL

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

PROVIGIL 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 PROVIGIL:
- Hormonal **contraceptives** (including the contraceptive pill, implants, intrauterine devices (IUDs) and patches). You will need to consider other birth control methods while taking PROVIGIL, and for two months after stopping treatment, because PROVIGIL reduces 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 breast-feeding, think you may be pregnant or are planning to have a baby, you should not take PROVIGIL. 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 PROVIGIL (and for two months after stopping) or if you have any other concerns.

Driving and using machines

PROVIGIL 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.

PROVIGIL 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.

PROVIGIL contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take PROVIGIL

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 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.

Elderly patients (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 kidney and 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.

If you take more PROVIGIL 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 heart beat or an increase in blood pressure.

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 PROVIGIL
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 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 more than 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 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)
- 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.
- Hay fever 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
- 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 HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PROVIGIL

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister and the carton 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 Provigil contains
The active substance is modafinil.
Each tablet contains 100 mg modafinil.

The other ingredients are:
lactose monohydrate (refer to section 2), pregelatinised starch (maize), microcrystalline cellulose, croscarmellose sodium, povidone K29/32, magnesium stearate.

What PROVIGIL looks like and contents of the pack
Provigil 100 mg tablets are capsule shaped, white to off-white colour, 13 x 6 mm with "100" on one side.
Provigil is available in blister packs of 30 tablets.

Manufacturer
Laboratoires Macors, Rue des Caillottes, Zl Plaine des Isles, 89000 Auxerre, France or Teva Operations Poland Sp. z.o.o. ul Mogilska 80, 31-546 Kraków, Poland.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Numbers:
PPA 465/415/1

PROVIGIL is a registered trademark of Teva Pharmaceuticals International GmbH

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: MODASOMIL
Czechia, Germany: VIGIL
Cyprus, Denmark, France, Greece, Iceland, Netherlands, Norway, Portugal, Spain: MODIODAL
Belgium, Ireland, Italy, Luxembourg, United Kingdom (Northern Ireland): PROVIGIL
Germany: VIGIL
Ireland: PROVIGIL

This leaflet was last revised in October 2022.