PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Provigil®

Caplets

Composition

Each caplet contains:
Modafinil 100 mg

For information about inactive and allergenic ingredients, see section 2 under the heading "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

Provigil lowers the effectiveness of hormonal contraceptive medicines. You must use additional effective methods of contraception throughout the period of treatment with Provigil and for two months after stopping treatment.

Use of this medicine could cause dependence to arise. Tell the doctor if, in the past, you have developed dependence on alcohol, drugs or medicines.

1. WHAT IS THE MEDICINE INTENDED FOR?

Provigil is intended for the treatment of sleepiness associated with narcolepsy, sleepiness associated with obstructive sleep apnea/hypopnea syndrome, sleep disorder due to shift work.

Provigil will not cure these sleep disorders. Provigil may help the sleepiness caused by these conditions, but it might not completely prevent it. Provigil is not intended to take the place of sufficient sleep. Follow the doctor's instructions about proper sleep habits and using other treatments.

Therapeutic group: Provigil belongs to a group of medicines that stimulate activity of the central nervous system.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) or have developed a rash in the past to the active ingredient modafinil, armodafinil (Nuvigil) or to any of the additional ingredients contained in the medicine (see section 6).

Special warnings regarding use of the medicine

This medicine could cause severe side effects, including a severe rash or a severe allergic reaction that could affect various parts of the body such as the liver or blood cells. These effects could be life-threatening and it may be necessary to go to hospital to have them treated. See further information in section 4 "Side Effects".

Before treatment with Provigil, tell the doctor if:

- You have suffered in the past from problems connected to mental health, including psychosis.
- You have heart problems or have had a heart attack.
- You have high blood pressure. Your blood pressure may need to be checked more often while being treated with Provigil.
- You suffer from kidney or liver problems.
- You have developed in the past dependence on or abuse of alcohol or medicines.
- You are pregnant or are planning pregnancy; see section 2 under the heading "Pregnancy, breastfeeding and fertility".
- You are breastfeeding; see section 2 under the heading "Pregnancy, breastfeeding and fertility".

Children and adolescents

Provigil is not approved for use in children under the age of 18 years for any medical condition, including the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Hormonal contraceptive medicines (including contraceptive pills, injections, hormonal implants, patches, vaginal rings and hormonal intrauterine device). The effectiveness of hormone-based methods of contraception may decrease while taking Provigil, and the chance of becoming pregnant while taking Provigil and for two months after stopping Provigil increases. Consult with the doctor about the choice of contraception method during the period of treatment with the medicine and for two months after stopping treatment.
- Phenytoin (for convulsions or epilepsy).
- Omeprazole (for the treatment of stomach problems such as ulcer).
- Warfarin (anticoagulant) – it is recommended to perform more frequent testing of PT/INR.
- Propranolol (for hypertension, heart problems or migraine).
- Ciclosporin (for the prevention of graft rejection).
- Diazepam, midazolam and triazolam (medicines from the benzodiazepine group).
- Clomipramine (for depression).
- Medicines for anxiety from the monoamine oxidase inhibitor (MAOI) group.
- Medicines from the tricyclic antidepressant (TCA) group.
- Selective serotonin reuptake inhibitor (SSRI)-type antidepressants.

Use of the medicine and food

Provigil can be taken with or without food.

Use of the medicine and alcohol consumption

Abstain from drinking alcohol. It is not known how drinking alcohol will affect you when you are taking Provigil.

Pregnancy, breastfeeding and fertility

Do not take Provigil if you are pregnant (or think you might be pregnant), planning to become pregnant or are breastfeeding. Provigil is suspected to cause congenital defects when taken during pregnancy.

Consult with the doctor about the contraceptive methods appropriate for you during the entire period of treatment and for two months after stopping use of the medicine, or if you have further questions (see additional information in section 2 under the heading "Drug interactions").

Driving and operating machinery

Do not drive a car or perform other dangerous activities until you know how the medicine affects you. People suffering from sleep disorders must always be careful not to perform actions that could be dangerous. Do not change your daily habits without approval from the doctor.

Important information about some of the ingredients of the medicine

Provigil contains lactose. If you have been told by your doctor that you are sensitive to certain types of sugar, consult with the doctor before taking this medicine.

This medicine contains less than 23 mg of sodium per caplet, and is therefore considered to be sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen with the medicine.

The dosage and treatment regimen will be determined by the doctor only.

- The doctor will prescribe you the dosage of Provigil that is suitable for you. Do not change the dosage without consulting with the doctor.
- The doctor will instruct you as to the appropriate time of day to take Provigil:
  - Patients with narcolepsy or obstructive sleep apnea (OSA) usually take Provigil one time each day in the morning.
  - Patients with sleep disorder due to shift work usually take Provigil about an hour before their work shift.
- Do not change the time of day at which you take Provigil unless you have consulted with your doctor. Taking Provigil too close to bedtime could cause difficulty in falling asleep.

Crushing/halving/chewing

Do not halve the caplet in the absence of a score line. There is no information regarding crushing/chewing the caplet.

Do not exceed the recommended dose.

This medicine is not intended for the treatment of children under the age of 18 years.

If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

Symptoms of an overdose of Provigil may include:

- Trouble sleeping.
- Restlessness.
- Confusion.
- Feeling disoriented.
- Feeling excited.
- Hearing, seeing, feeling or sensing things that are not really there (hallucinations).
- Nausea and diarrhea.
- Fast or slow heartbeat.
- Chest pain.
- Increased blood pressure.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult the doctor. Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Provigil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking the medicine and refer immediately to a doctor or proceed to an emergency room, if the following appear:

- **Severe skin rash or severe allergic reaction:**
  - Skin rash, itchy rash, sores in the mouth, blisters and peeling of the skin.
  - Swollen face, eyes, lips, tongue or throat.
  - Difficulty swallowing or breathing.
  - Fever, shortness of breath, swelling of the legs, yellowing of the skin or whites of the eyes, or dark urine.

If you suffer from a severe rash, stopping the use of Provigil will not necessarily prevent the rash from becoming life-threatening or from causing you to be permanently disabled or disfigured.

- **Mental (psychiatric) symptoms, including:**
- Depression.
- Feeling anxious.
- Hearing, seeing, or feeling things that are not really there (hallucinations).
- An extreme increase in activity and talking (mania).
- Suicidal thoughts.
- Aggressive behavior.
- Other mental problems.
- **Symptoms of a heart problem,** including chest pain, irregular heartbeat and breathing difficulties.

Common side effects:

- Abnormal laboratory tests
- Increase in certain liver enzymes
- Headache
- Diarrhea
- Back pain
- Feeling anxious
- Sleeping difficulties
- Nausea
- Feeling irritable
- Dizziness
- Stuffy nose
- Abdominal pain

Additional side effects:

Anorexia, dry mouth, pharyngitis, chest pain, hypertension, abnormal liver function, constipation, depression, palpitations, paresthesia (tingling and prickling sensation), falling asleep, rapid heart rate, widening of blood vessels (vasodilation), abnormal vision, irritability, asthma, chills, confusion, dyskinesia (involuntary muscle movements), swelling, emotional instability, eosinophilia (white blood cells in the blood), nosebleed, flatulence, hyperkinesia (excessive movement), hypertonia (high muscle tone), mouth ulcer, sweating, altered sense of taste, thirst, tremor, urinary disturbances, vertigo.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

Circulatory system: Agranulocytosis.

Psychiatric disorders: Psychomotor hyperactivity.

Certain effects of Provigil on the brain are similar to those that occur with other medicines that are considered to be "stimulants". These effects could lead to abuse of or dependence on Provigil.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions: Store below 25°C.**

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Lactose monohydrate, pregelatinized starch, microcrystalline cellulose, povidone, croscarmellose sodium, magnesium stearate.

What the medicine looks like and contents of the package

A white-cream-colored caplet, smooth on one side and with the number '100' engraved on the other side.

Each package contains 10, 30, 60 or 90 caplets in blister packs. Not all package sizes may be marketed.

Name of License Holder and Address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St.,Tel Aviv 6944020.

Name of Manufacturer and Address:

Teva Pharma B.V., Utrecht, The Netherlands.

This leaflet was revised in January 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 124.37.30383