Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Modafinil Medochemie
Tablets

Active ingredient
Each tablet contains:
modafinil 100 mg

For information on inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar to yours.

Modafinil Medochemie reduces the efficacy of hormonal contraceptives. You should use additional effective contraceptive methods throughout the period of treatment with Modafinil Medochemie and for two months after treatment discontinuation.

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 this medicine intended for?

Modafinil Medochemie is intended for the treatment of sleepiness associated with narcolepsy, sleepiness associated with obstructive sleep apnea/hypopnea syndrome, and sleep disturbance due to shift work.

Modafinil Medochemie will not cure these sleep disturbances. Modafinil Medochemie can relieve sleepiness caused by these conditions, but may not completely prevent it. Modafinil Medochemie is not intended to replace sufficient sleep. Follow the doctor's instructions regarding appropriate sleeping habits and use of other therapies.

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

2. Before using this medicine

Do not use this medicine if:
- you are sensitive (allergic) or have previously developed a rash as a reaction to the active ingredient modafinil, to armodafinil or to any of the other ingredients in this medicine (see section 6).
- you are pregnant or breastfeeding.

Special warnings about using this medicine

This medicine may cause severe side effects, including severe rash or a severe allergic reaction which may affect various body organs such as the liver or blood

cells. These effects may be life-threatening and may require arrival to the hospital to treat them. See further information in section 4 "Side effects".

Before using Modafinil Medochemie, tell your doctor if:
- you have previously suffered from problems related to mental health, including psychosis.
- you have heart problems or have suffered a heart attack.
- you have high blood pressure. More frequent blood pressure tests may be required during the period of treatment with Modafinil Medochemie.
- you suffer from kidney or liver problems.
- you have previously developed alcohol or medicine dependence or abuse.
- you are pregnant or planning to become pregnant, see section 2 under "Pregnancy, breastfeeding and fertility".
- you are breastfeeding, see section 2 under "Pregnancy, breastfeeding and fertility".

Children and adolescents
Modafinil Medochemie is not approved for use in children and adolescents below the age of 18 years for any medical condition, including treatment for 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. Particularly if you are taking:
- Hormonal contraceptives (including contraceptive pills, injections, hormonal implants, transdermal patches, vaginal rings and hormonal intrauterine device). The efficacy of hormone based contraceptives may be reduced during Modafinil Medochemie intake, and the chance of getting pregnant while taking Modafinil Medochemie and for 2 months after Modafinil Medochemie discontinuation increases. Consult the doctor regarding the choice of contraceptive method during the period of treatment with the medicine and up to 2 months after treatment discontinuation.
- Phenytoin (for convulsions or epilepsy).
- Omeprazole (for treatment of stomach problems such as a gastric ulcer).
- Warfarin (an anticoagulant); more frequent PT/INR tests are recommended.
- Propranolol (for hypertension, heart problems or migraine).
- Cyclosporine (for prevention of transplant rejection).
- Diazepam, midazolam and triazolam (medicines of the benzodiazepine class).
- Clomipramine (for depression).
- Medicines against anxiety of the monoamine oxidase inhibitor class (MAOIs).
- Medicines of the tricyclic antidepressant class (TCA).
- Selective serotonin reuptake inhibitor (SSRI)-type antidepressants.

Using this medicine and food
Modafinil Medochemie can be taken with or without food.

Using this medicine and alcohol consumption
Avoid drinking alcohol. It is not known how alcohol will affect you while taking Modafinil Medochemie.

Pregnancy, breastfeeding and fertility
Do not take Modafinil Medochemie if you are pregnant (or think you may be pregnant), planning to become pregnant or are breastfeeding. Modafinil Medochemie is suspected to cause congenital defects when taken during pregnancy.

Consult the doctor regarding contraceptive methods suitable for you throughout the treatment period and for 2 months after discontinuing treatment with the medicine, or if you have further questions (see further information in section 2 under "Drug interactions").

Driving and using machines
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 ensure avoiding activities which may be dangerous.
Do not change your daily habits without the doctor's approval.

Important information about some of this medicine's ingredients
Modafinil Medochemie contains lactose. If you have been told by your doctor that you have intolerance to certain sugar types, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.

- The doctor will prescribe to you the Modafinil Medochemie dosage suitable for you. Do not change the dosage without consulting the doctor.
- The doctor will instruct you regarding the suitable time of the day for taking Modafinil Medochemie.
    - Patients with narcolepsy or obstructive sleep apnea (OSA) usually take Modafinil Medochemie once daily in the morning.
    - Patients with sleep disturbance due to shift work usually take Modafinil Medochemie about 1 hour before their work shift.
- Do not change the time of Modafinil Medochemie intake unless you have consulted your doctor. Taking Modafinil Medochemie too close to bedtime may cause difficulties falling asleep.

Do not exceed the recommended dose.

Crushing/splitting/chewing
Do not split the tablet in the absence of a score line. There is no information about tablet crushing/chewing.

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

Symptoms of Modafinil Medochemie overdose may include:

- Sleeping problems
- Restlessness
- Confusion
- Lack of orientation
- Sensation of excitement
- Hearing, seeing, feeling or sensing things that are not real (hallucinations)
- Nausea and diarrhea
- Rapid or slow pulse
- Chest pain
- Increase in 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 scheduled time and consult the doctor. Adhere to the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Modafinil Medochemie may cause side effects in some users. Do not be alarmed by this list of side effects. You may not suffer from any of them.

Stop taking this medicine and consult your doctor immediately or proceed to an emergency room if the following effects appear:

Severe skin rash or severe allergic reaction
- Skin rash, itchy rash, sores in the mouth, blistering and peeling of the skin
- Swelling of the face, eyes, lips or throat
- Difficulties swallowing or breathing
- Fever, dyspnea, swelling of the legs, yellowing of the skin or white parts of the eyes, or dark urine

If you suffer from severe rash, discontinuation of Modafinil Medochemie use will not necessarily prevent the rash from becoming life-threatening or causing disability or permanent disfigurement.

Mental (psychiatric) symptoms, including:
- Depression
- Feeling of anxiety
- Hearing, seeing, or feeling things that are not real (hallucinations)
- Extremely enhanced activity and speech (mania)
- Suicidal thoughts
- Aggressive behavior
- Other mental problems

Symptoms of a heart problem, including chest pain, irregular pulse and difficulties breathing.

<u>Common side effects:</u>
- Laboratory test abnormalities
- Increase in certain liver enzymes
- Headache
- Diarrhea
- Back pain
- Feeling of anxiety
- Difficulties sleeping
- Nausea
- Feeling of irritability
- Dizziness
- Nasal congestion
- Abdominal pain

Additional side effects:
Loss of appetite (anorexia), dry mouth, pharyngitis, chest pain, hypertension, abnormal liver function, constipation, depression, palpitations, paresthesia (tingling and prickling), somnolence, rapid heart rate, vasodilatation, abnormal vision, irritability, asthma, chills, confusion, dyskinesia (involuntary muscle movements), edema, emotional instability, eosinophilia (high level of white blood cells), nosebleed, bloating, hyperkinesia (excessive movement), hypertonia (high muscle tone), oral ulcers, sweating, changes in the sense of taste, thirst, tremor, urinary disorders, vertigo.

Side effects of unknown frequency (the frequency of has not been determined yet):
Circulatory system: agranulocytosis.
Psychiatric disorders: psychomotor hyperactivity.

Certain effects of Modafinil Medochemie on the brain are similar to those of other medicines considered as "stimulants". These effects may lead to Modafinil Medochemie abuse or dependence.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link “Reporting side effects following 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 to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed 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. Additional information

In addition to the active ingredient, this medicine also contains:
Lactose monohydrate, maize starch, croscarmellose sodium, aluminium magnesium silicate, povidone K90, talc, magnesium stearate.

What the medicine looks like and contents of the pack:
A white, round and biconvex tablet.
Each pack contains 20, 30, 60 or 90 tablets in blisters.
Not all pack sizes may be marketed.

Registration holder's name and address: Devries and Co. Ltd., 32 Habarzel St., Tel Aviv.

Manufacturer's name and address:
Medochemie Ltd., 1-10 Constantinoupoleos street, 3011, Limassol, Cyprus

Revised in May 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 163-27-35354