

Modiodal[®] 100_{mg}, tablet 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 or if you have a doubt, 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What MODIODAL is and what it is used for
2. Before you use MODIODAL
3. How to take MODIODAL
4. Possible side effects
5. How to store MODIODAL
6. Further information

1. WHAT MODIODAL IS AND WHAT IT IS USED FOR

The active substance in the tablets is modafinil.

Modafinil can be taken by adults who suffer from narcolepsy to help them 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 frequency of sleep attacks; however, there may also be other ways that you can improve your condition and your doctor will advise you.

2. BEFORE YOU USE MODIODAL

If your doctor has told you that you are intolerant to certain sugars, contact him/her before starting to take this medicine.

Do not take MODIODAL in the following cases:

- If you are allergic (hypersensitive) to modafinil or any of the other ingredients of these tablets (see section 6 "What MODIODAL contains"),
- If you have an irregular heart rate (heartbeat),
- If you have uncontrolled, moderate to severe high blood pressure (hypertension).

Take special care with MODIODAL:

- If you have any **heart problems or high blood pressure**. Your doctor will need to check these regularly while you are taking MODIODAL.
- If you 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 MODIODAL could make your condition worse.
- If you have **kidney** or **liver** problems (in this case, you will need to take a lower dose).
- If you have had **alcohol or drug problems** in the past.

The use of this medicine is not advised in patients with galactose intolerance, Lapp lactase deficit or glucose or galactose malabsorption syndrome (rare hereditary diseases).

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

Other information to be given to your doctor or pharmacist:

- Some people have reported having **suicidal or aggressive thoughts or behaviour** when 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 if you notice 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 can cause dependence in the event of long-term use. If you need to take it for a long time, your doctor will check regularly that MODIODAL is still the best medicine for you.

Using or 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. MODIODAL and certain other medicines can affect each other and your doctor may need to adjust the doses that you are taking. This is especially important if you are taking any of the following medicines as well as MODIODAL:

- Hormonal **contraceptives** (including the contraceptive pill, implants, intrauterine devices (IUDs) and patches). You will need to consider other birth control methods while taking MODIODAL, and for two months after stopping treatment, because MODIODAL reduces their effectiveness.
- **Omeprazole** (used to treat gastric reflux, indigestion or ulcers).
- Antiretroviral drugs to treat HIV infection (protease inhibitors, e.g. indinavir or ritonavir).
- **Ciclosporin** (used to prevent organ transplant rejection or to treat arthritis or psoriasis).
- Medicines used to treat **epilepsy** (e.g. carbamazepine, phenobarbital or phenytoin).
- Medicines used to treat **depression** (e.g. amitriptyline, citalopram or fluoxetine) or **anxiety** (e.g. diazepam).
- Medicines used to thin the blood (e.g. **warfarin**). Your doctor will monitor your blood clotting times during treatment.
- Calcium channel blockers or beta-blockers used to treat **high blood pressure** or heart problems (e.g. amlodipine, verapamil or propranolol).
- Statins, used to lower **cholesterol** (e.g. atorvastatin or simvastatin).

Taking MODIODAL with Food and Drink

Food have no influence.

Pregnancy and breastfeeding

If you are pregnant (or think that you may be), are planning to become pregnant, or are breastfeeding, you should not take MODIODAL. It is not known whether this medicine may harm your unborn baby.

Talk to your doctor about the birth control methods that you should use while you are taking MODIODAL (and for two months after stopping) or if you have any other concerns.

Athletes and sportsmen

Warning: this medicine contains modafinil which is included in the list of doping substances.

Driving and using machines

Medicines containing modafinil can cause blurred vision or dizziness (affecting up to 1 in 10 patients). If you are affected or if you find that while using this medicine you still feel very sleepy, do not attempt to drive or operate machinery.

Important information about some of the ingredients of MODIODAL:

This medicine contains lactose.

3. HOW TO TAKE MODIODAL

Dosage

Always comply with the dosage indicated by your doctor. Check with your doctor or pharmacist if you are not sure.

The whole tablet should be swallowed with water.

Adults

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

In some cases, your doctor may decide to increase your daily dose up to 400 mg.

Elderly patients (over 65 years of age)

The usual dosage is 100 mg per day. This can be taken once daily (in the morning) or divided into two doses per day (50 mg in the morning and 50 mg at midday). Your doctor may only increase your dose (up to a maximum of 400 mg per day) provided that you do not have any liver or kidney problems.

Adults with severe kidney or liver problems

The usual dosage is 100 mg per day.

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

If you take more MODIODAL than you should:

If you take too many tablets you may feel sick, restlessness, disorientated, confused or excited. You may also have difficulty sleeping, diarrhoea, hallucinations (seeing or hearing things that are not real), chest pain, a change in the speed of your heartbeat or an increase in blood pressure. Contact your nearest hospital emergency department or tell your doctor or pharmacist immediately. Take this leaflet and any remaining tablets with you.

If you forget to take MODIODAL:

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 dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, MODIODAL 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). Blood test results may be abnormal.
- You feel any change in your mental health. The signs may include:
 - o mood swings or abnormal thinking,
 - o aggression or hostility,
 - o forgetfulness or confusion,
 - o feeling of extreme happiness,
 - o over-excitement or hyperactivity,
 - o anxiety or nervousness,
 - o depression, suicidal thoughts or behaviour,
 - o agitation or psychosis (loss of contact with reality, which may include delusions or hallucinations (seeing or hearing things that are not real), feeling detached or numb or personality disorders.

Other side effects include the following:

Very common side effects (affecting more than 1 in 10 patients)

- Headaches

Common side effects (affecting fewer than 1 in 10 patients)

- Dizziness.
- Drowsiness, extreme tiredness or difficulties sleeping (insomnia).
- Awareness of your heartbeat, which may be faster than normal.
- Chest pain.
- Hot flushes.
- 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 for liver function tests (increased liver enzymes).

Uncommon side effects (affecting fewer than 1 in 100 patients)

- Back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching muscles 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.
- Excessive 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, excessive thirst or taste alteration.

- Vomiting.
- Migraine.
- Elocution difficulties (speech problems).
- Diabetes with increased blood sugar.
- High blood cholesterol.
- Swollen hands and feet.
- Disrupted sleep or abnormal dreams.
- Loss of sex drive.
- Nosebleeds, sore throat or inflamed nasal passages (sinusitis).
- Abnormal vision or dry eyes.
- Abnormal urine or more frequent urination.
- Abnormal periods.
- Abnormal blood test results (change in white cell count).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE MODIODAL

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date stated on the blister strip and outer packaging after "EXP". The expiry date refers to the last day of that month.

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.

Store in a dry place below 30°C.

6. FURTHER INFORMATION

What MODIODAL contains

Each tablet contains modafinil (100 mg) as the active substance. The tablets also contain: lactose monohydrate, pregelatinised starch, microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate as inactive ingredients.

What MODIODAL looks like and contents of the pack

MODIODAL comes in the form of an oblong, white to off-white tablet, with "100" on one side.

Pack of 30 tablets.

Manufacturer

Laboratoires Macors
Rue des Caillottes
ZI Plaine des Isles
89000 Auxerre
France

Marketing Authorization Holder

Acino Pharma AG
Birsweg 2
4253 Liesberg
Switzerland

For any information about this medicine, please contact the local representative of the Marketing Authorization Holder:

Biologix FZ co

Dubai Free Zone, Road WB 21, Warehouse, C17 PO Box 54405.

AL Tawar Dubai, United Arab Emirates

Telephone number: 00971 4 299 7171

Or to the email address Pharmacovigilance@blgx.net

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To report any side effect(s):

• Saudi Arabia:

- National Pharmacovigilance and Drug Safety Center (NPC)

Call NPC at +966-11-2038222,

Exts: 2317-2356-2353-2354-2334-2340

- Fax: +966-11-205-7662
- Toll-free: 8002490000
- Email: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

• United Arab Emirates:

- Ministry of Health

Registration and Drug Control Department

- Tel: +971-2-6117 389 / 329 / 391 / 318
- Fax: +971-2-6313742
- P.O. Box: 848 Abu Dhabi
- Email: pv@moh.gov.ae
- Website: www.cpd-pharma.ae

• Other GCC States

- Please contact the relevant competent authority.

This is a Medicament

- **Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.**
- **The doctor and the pharmacist are the experts in medicines, their benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribed for you.**
- **Do not repeat the same prescription without consulting your doctor.**

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Detailed information about this medicine is available on the ANSM website (France).