

Scheduling Status:

S5

Modafinil 100 iPharma, tablets Modafinil

Contains sugar (lactose monohydrate 49,4 mg per tablet)

Read all of this leaflet carefully before you start taking Modafinil iPharma.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Modafinil 100 iPharma has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

1. What Modafinil iPharma is and what it is used for:

Modafinil iPharma contains the active substance modafinil. Modafinil is a central nervous system (CNS) stimulant which increases alertness.

Modafinil iPharma 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), which is caused by the brain's inability to regulate sleep-wake cycles normally.

2. What you need to know before you take Modafinil 100 iPharma:

Do not take Modafinil 100 iPharma if:

- you are hypersensitive (allergic) to modafinil or any of the other ingredients of Modafinil iPharma (listed in section 6)
- you suffer from major anxiety

- you are a child or adolescent under the age of 16 years
- you suffer from kidney failure / impairment
- you have uncontrolled, moderate to severe high blood pressure (hypertension)
- you have an irregular heartbeat

Warnings and precautions:

Take special care with Modafinil iPharma:

- If you are taking Modafinil iPharma you should be seen by a specialist on a regular basis to be clinically assessed
- You should notify your doctor immediately if you develop any kind of rash, hives or any allergic reaction as there have been reports of rare cases of a severe life-threatening allergic reaction (Stevens Johnson syndrome)
- If you suffer from major anxiety Modafinil iPharma should only be administered in a specialist unit under the care of a specialist
- If you have a history of psychosis Modafinil iPharma should be used with caution
- If you suffer from high blood pressure your heart rate should be monitored
- You should not take Modafinil iPharma if you have a history of heart enlargement, abnormal/irregular heartbeats, changes in your ECG or other heart problems as the risk of developing similar effects may be increased with the use of Modafinil iPharma
- If you had a recent history of heart attack or unstable chest pain, you should be treated with caution under close supervision of your doctor
- Modafinil iPharma can cause wakefulness and therefore you should be cautious if taking Modafinil iPharma if you suffer from staying asleep
- If you are using hormonal contraceptives, you should use alternative or additional methods of contraception during and for one month after you stop taking Modafinil iPharma as modafinil may reduce the effectiveness of hormonal contraceptives. Continuation of the oral contraceptive for two cycles after stopping Modafinil iPharma is necessary for adequate contraception
- If you suffer from severe liver impairment you should take a lower dose of Modafinil iPharma
- If you are an elderly patient a lower dose should be prescribed by your doctor as your kidney and liver function may be lower
- As with other central nervous system stimulants, there is the possibility of dependence with the long-term use of Modafinil iPharma
- You should not take any alcohol while using Modafinil iPharma as the combination of these two substances has not been tested

Children and adolescents

Modafinil iPharma should not be given to individuals under the age of 16.

Other medicines and Modafinil iPharma

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

- Modafinil iPharma may increase blood levels and strengthen the effect of medicines such as diazepam (used for anxiety), phenytoin (used for epilepsy), omeprazole (used for acid reflux, indigestion or ulcers) and propranolol (used for high blood pressure or heart problems) when used in combination.
- Blood levels of medicine used to treat epilepsy should be monitored with care with the combined use with Modafinil iPharma as blood levels of the anti-epileptic medicine may change. If you are using a medicine called phenytoin used to treat fits and seizures, you should be monitored by your doctor for signs of phenytoin toxicity.
- The effectiveness of oral contraceptives may be impaired by Modafinil iPharma. An oral contraceptive product containing 50 micrograms or more of ethinyl oestradiol should be taken. Continuation of the oral contraceptive for two cycles after stopping Modafinil iPharma is necessary for adequate contraception.
- Blood levels and the effect of certain types of medicine like tricyclic antidepressants (e.g. amitriptyline) and selective serotonin reuptake inhibitors (e.g. citalopram or fluoxetine) used in patients with a certain enzyme deficiency (CYP2D6) for the treatment of depression, may be increased when used in combination with Modafinil iPharma. Your doctor will have to adjust your dose.
- If you are using Modafinil iPharma in combination with warfarin, it is recommended that your doctor monitor your prothrombin times as a precaution for the first several months and thereafter whenever Modafinil iPharma dosing is changed.
- Modafinil iPharma may lead to lower blood levels and weakening of the effect of ciclosporin (used in organ transplants, arthritis or psoriasis), antiviral medicines for the treatment of HIV (protease inhibitors e.g. indinavir or ritonavir), medicines for anxiety and sleeping problems (e.g., buspirone, triazolam or midazolam), medicines for high blood pressure and heart problems (calcium channel blockers e.g. amlodipine or verapamil), and cholesterol-lowering medicines (statins e.g. atorvastatin or simvastatin).
- Other medicines that increase the effect of an enzyme system known as cytochrome P-450 isoenzymes such as carbamazepine and phenobarbital used for epilepsy, could decrease the blood levels and weaken the effect of Modafinil iPharma.

Modafinil iPharma with food and alcohol

Food may delay the absorption of Modafinil iPharma by approximately one hour, but it does not affect the availability of the medicine in your body.

Use with caution if you have a history of alcohol or drug abuse.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare provider for advice before taking Modafinil iPharma.

Do not take Modafinil iPharma if you are pregnant or breastfeeding your baby.

Modafinil iPharma 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 Modafinil iPharma (and for two months after stopping).

Driving and using machines

Modafinil iPharma can cause blurred vision or dizziness. Modafinil iPharma could affect your ability to drive or operate machinery and you should not engage in such activities until the effect of the medicine on you are clear.

It is not always possible to predict to what extent Modafinil iPharma may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which Modafinil iPharma affects you.

3. How to take Modafinil iPharma

Do not share medicines prescribed for you with any other person.

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

The usual dose of Modafinil iPharma is 200 mg/day, taken in the morning as a single dose.

Doses of 400 mg/day, given as a single dose, is well tolerated, but there is no consistent evidence that this dose offers additional benefit beyond that of the 200 mg dose.

If you are an elderly patient your dose may have to be reduced by your doctor

If you suffer from liver failure your dose will have to be reduced by half ((100 to 200 mg/day).

Your doctor will tell you how long your treatment with Modafinil iPharma will last. If you have the impression that the effect of Modafinil iPharma is too strong or too weak, tell your doctor or pharmacist.

If you take more Modafinil iPharma than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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, chest pain, a change in the speed of your heartbeat or an increase in blood pressure.

If you forget to take Modafinil iPharma

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 forgotten individual doses.

4. Possible side effects:

Modafinil iPharma can have side effects.

Not all side effects reported for Modafinil iPharma are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Modafinil iPharma, please consult your healthcare provider for advice.

If any of the following happens, stop taking Modafinil iPharma and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Modafinil iPharma. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 high temperature 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- decreased appetite
- sleeplessness
- headache, dizziness
- weakness, numbness or tingling of the hands or feet (pins and needles)
- blurred vision
- awareness of your heartbeat, which may be faster than normal
- widening of blood vessels
- stomach pain, nausea, dry mouth, diarrhoea, indigestion, constipation
- chest pain
- lack of energy
- abnormal blood test results showing how your liver is working (increased liver enzymes)

Less frequent side effects

- inflammation /infection of the throat, sinus infection
- increase in white blood cells known as eosinophilia
- a low level of white blood cells in the blood, which can interfere with the ability to fight infection
- high blood sugar, high cholesterol, increased appetite
- sleep disorder, abnormal dreams, decreased sex drive, hallucinations
- difficulty moving muscles smoothly or other movement problems, muscle tension, coordination problems
- loss of memory, migraine, a spinning sensation (vertigo)
- a decreased sense of touch or sensation, speech disorder, altered or impaired sense of taste
- abnormal vision, dry eye, lazy eye
- abnormal heart beats, irregular heartbeat, abnormally slow heart rate

- low or high blood pressure
- increased cough, asthma or shortness of breath, nose bleeds, runny nose
- flatulence, heartburn, mouth sores, inflammation of the tongue, vomiting, difficulty swallowing
- skin rash, acne or itchy skin
- sweating
- back pain, neck pain, muscle pain, muscle weakness, leg cramps, joint pain, twitching or tremor
- abnormal urine, more frequent urination, abnormal ejaculation
- menstrual disorder
- swelling of the legs and arms, thirst
- abnormal ECG and weight increase or decrease

Side effects with unknown frequency

- infection, low body temperature, flu syndrome
- an increase in the number of white cells in the blood, especially during an infection
- deficiency in the number or quality of red blood cells in your body
- a sudden, brief loss of voluntary muscle tone triggered by strong emotions such as laughter
- ear pain, ear disorders
- inflammation of the lining of bronchial tubes, which carry air to and from the lungs, lung infection
- tooth disorders, vomiting, inflamed gums, loss of appetite
- a discoloration of the skin resulting from bleeding underneath, typically caused by bruising.
- itchy skin, dry skin, skin disorders, chronic immune –mediated skin disease (psoriasis)
- an infection in any part of the urinary system, the kidneys, bladder or urethra, pus in the urine, blood in the urine, bladder inflammation
- painful menstruation
- increased liver enzymes (AST)
- accidental injury

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications. By reporting side effects, you can help provide more information on the safety of Modafinil 100 iPharma.

5. How to store Modafinil iPharma:

Store all medicine out of reach of children.

Store at or below 25 °C.

Store in the original packaging until required for use.

Do not use the tablets after the expiry date shown on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What Modafinil iPharma contains:

The active ingredient is modafinil. Each tablet contains 100 mg modafinil.

The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K29/32, pregelatinised starch, talc.

What Modafinil iPharma looks like and contents of the pack:

White, circular, biconvex tablet and without irregularities, 9 mm.

Modafinil iPharma tablets are packed in heat-sealed PVC – Aluminium blister packs.

Blister strips of Modafinil iPharma tablets are packed together with the leaflets in cardboard cartons of 30 tablets.

Holder of Certificate of Registration:

iPharma (Pty) Ltd

124 Elevation Avenue, Randjesfontein

Midrand, 1683, South Africa

Tel. no.: (011) 314 2366

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