

APO-Modafinil Tablets

Contains the active ingredient modafinil

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

This medicine contains the active ingredient modafinil.

It is used:

- to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy
- to treat excessive sleepiness associated with moderate to severe chronic shift work sleep disorder (SWSD), where non-drug therapies have been inappropriate or unsuccessful.
- as an adjunct to continuous positive airways pressure (CPAP) in obstructive sleep apnoea/hypopnoea syndrome (OSAHS) to improve wakefulness.

It is not known how modafinil works, but it is known that it acts on the central nervous system (the brain). It differs from other stimulant medicines that promote wakefulness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing modafinil
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine if you are pregnant, planning to become pregnant or likely to become pregnant.

If you could become pregnant, you should confirm by a pregnancy test that you are not pregnant within a week prior to starting treatment.

Modafinil is suspected to cause birth defects if taken during pregnancy. You should ensure that you have reliable and effective methods of contraception.

Do not take this medicine if you are breastfeeding.

It is not known whether modafinil passes into breastmilk and may affect your developing baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- are under 18 or over 65 years old
- history of mental health problems such as depression, anxiety or bipolar disorder
- heart problems, including angina (chest pain), previous heart attack or enlarged heart
- abnormal/irregular heart rhythms
- high blood pressure or your high blood pressure is controlled by medication

- kidney or liver problems

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and modafinil may interfere with each other. These include:

- hormonal contraceptives
- brain stimulants, such as methylphenidate
- medicines used to treat depression, including monoamine oxidase inhibitors (MAOIs)
- medicines to treat epilepsy, such as phenytoin, carbamazepine, or phenobarbitone
- medicines to treat fungal infections, such as ketoconazole and itraconazole
- rifampicin, an antibiotic used to treat tuberculosis
- cyclosporin, used to treat organ transplant rejection

- propranolol, used to treat high blood pressure or heart failure
- warfarin, used to prevent blood clotting
- theophylline, used to treat asthma and lung problems
- medicines to help you sleep (sedatives)

These medicines may be affected by modafinil or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

How to take it

Swallow the tablets whole with a glass of water.

It does not matter if you take it before, with or after food.

When to take it

For sleepiness associated with narcolepsy or OSAHS, you should take modafinil tablets as either:

- two separate doses, one in the morning and one at midday
OR
- one dose, in the morning.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

If you could become pregnant, you should confirm by a pregnancy test that you are not pregnant within a week prior to starting treatment.

Tell your doctor if you become pregnant, are planning to become pregnant or start to breastfeed while taking this medicine.

Tell your doctor if you believe that modafinil is not helping your condition. Your doctor may need to change the dose.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness in some people.

Modafinil may reduce the effectiveness of hormonal contraceptives (including the contraceptive pill, implants, injectables and some intrauterine devices (IUDs)).

If you are using hormonal contraception, you should use an alternative non-hormonal method of birth control together with your current contraceptive whilst taking modafinil and for 2 months after you stop treatment with modafinil.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea
- headache
- diarrhoea
- dry mouth
- poor appetite
- runny nose
- sore throat
- nervous feeling
- dizziness
- back pain
- feeling anxious
- upset stomach
- indigestion
- trouble sleeping

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the skin or white of the eyes, dark urine
- mental (psychiatric) symptoms including depression, anxiety, aggression, agitation, irritability, hallucinations, mania, thoughts of suicide or other mental problems
- chest pain or abnormal heart beats
- fits or convulsions

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fever, skin rash, hives (especially affecting the whole body)
- sores in your mouth, or your skin blisters and peels
- sudden wheeziness, difficulty in breathing and swallowing
- fever, shortness of breath, swelling of the legs
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-MODAFINIL Tablets look like

100 mg tablet

White, round, biconvex tablets. Engraved “MOD” over “100” on one side, “APO” on the other side. AUST R 276420.

Available in blister packs of 30 and 60 tablets

* Not all pack sizes may be available.

Ingredients

Each tablet contains 100 mg of modafinil as the active ingredient.

It also contains the following inactive ingredients:

- methylcellulose
- croscarmellose sodium
- magnesium stearate
- colloidal anhydrous silica

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Sponsor

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