

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

The medicine is dispensed with
a doctor's prescription only

Nuvigil 50 mg

Tablets

Composition

Each tablet contains:
armodafinil 50 mg

Nuvigil 150 mg

Tablets

Composition

Each tablet contains:
armodafinil 150 mg

Nuvigil 250 mg

Tablets

Composition

Each tablet contains:
armodafinil 250 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 medical condition
is similar.

**This medicine is not intended for use
in children or adolescents under 18
years of age.**

**The medicine may reduce the
effectiveness of hormonal birth
control methods.** You must use additional
effective birth control methods. **See under
the heading "Drug interactions" in
section 2 of this leaflet.**

1. WHAT IS THE MEDICINE INTENDED FOR?

Nuvigil is intended to improve wakefulness
in adults with excessive sleepiness
associated with one of the following
diagnosed sleep disorders:

- Narcolepsy – uncontrollable daytime
sleeping bouts.
- Sleep disorder due to obstructive sleep
apnea (OSA), in combination with other
treatments. Nuvigil does not take the
place of a CPAP machine or other
treatments prescribed by the doctor. It is
important to continue these treatments
as prescribed by the doctor.
- Sleep disorder due to working in shifts
(shift work disorder – SWD).

Nuvigil will not cure these sleep disorders.
Nuvigil may relieve the sleepiness caused
by these conditions, but it may not prevent
it entirely. Nuvigil 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:
The active ingredient in Nuvigil tablets is
armodafinil, which belongs to the family
of sympathomimetic preparations, that act
on the central nervous system.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the
active ingredient or to any of the
additional ingredients contained in
the medicine (see section 6 "Further
Information").
- You are sensitive (allergic) to
modafinil – Provigil.
- You have had a rash or allergic
reaction to armodafinil (Nuvigil) or to
modafinil (Provigil). These are very
similar medicines.

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 part 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 in section
4 "Side Effects" under the heading
"Stop taking the medicine and refer
to a doctor immediately if the following
occur".**

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

**Before starting treatment with the
medicine, inform the doctor in detail of
all that you know about your medical
condition, including if:**

- You have suffered in the past from
problems connected to mental health,
including psychosis.
- You suffer from heart problems or have
suffered a heart attack.
- You suffer from high blood pressure.
Your blood pressure may need to be
checked more often during treatment
with Nuvigil.
- You suffer from liver or kidney problems.
- You have suffered in the past from
dependence on or addiction to alcohol
or medicines.
- You are pregnant or are planning
pregnancy; see in "Pregnancy,
breastfeeding and fertility" section.
- You are breastfeeding; see in
"Pregnancy, breastfeeding and fertility"
section.

Use in children

This medicine is not approved for use in
children or adolescents for any medical
condition.

The effectiveness and safety of the
medicine have not been tested in children
under 18 years of age.

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:

Important

- If you are using hormonal birth control
methods, such as birth control pills,
shots, implants, patches, vaginal
rings or intrauterine devices (IUDs),
tell the doctor. The effectiveness of
hormonal birth control methods may
be reduced while taking Nuvigil, and
the chance of getting pregnant while
taking Nuvigil and for two months after
stopping Nuvigil increases. You must
use additional effective methods of
birth control while taking Nuvigil and for
two months after taking the last dose.
Consult the doctor about choosing birth
control methods during the period of
treatment with the medicine, until two
months after stopping treatment.
- Phenytoin (for seizures or epilepsy).
- Omeprazole (to treat 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 (to prevent graft rejection).
- Diazepam, midazolam and triazolam
(medicines from the benzodiazepine
group).
- Clomipramine (for depression).
- Medicines for anxiety from the
monoamine oxidase inhibitor (MAOI)
group.

Use of the medicine and food

Nuvigil can be taken with or without food.

Use of the medicine and alcohol consumption

Abstain from drinking alcohol. The effect
of alcohol while taking Nuvigil is unknown.

Pregnancy, breastfeeding and fertility

Do not take Nuvigil if you are pregnant (or
think you might be pregnant), planning
to become pregnant or breastfeeding.
Nuvigil is suspected to cause congenital
defects when taken during pregnancy.
Consult a doctor about the methods of
birth control that are most appropriate
for you while taking Nuvigil and for
two months after stopping use of the
medicine, and about additional questions
that you have (see additional information
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 disturbances must always
make sure not to perform activities that
may be dangerous. Do not change your
daily habits without approval from the
doctor.

Important information about some of the ingredients of the medicine

This medicine contains lactose and
may cause allergy in people sensitive
to lactose. If you have been told by your
doctor that you have an intolerance to
certain sugars, contact your doctor before
taking this medicine.

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use 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.

Take the medicine precisely as prescribed
by the doctor. Do not change the dosage
without consulting the doctor.

The doctor will instruct you as to the
proper time of day to take Nuvigil. Do not
change this time without consulting the
doctor. Taking this medicine too close
to bedtime could cause difficulty falling
asleep.

The usual dosage is generally:

- Narcolepsy and sleep disorders due to
obstructive sleep apnea: 150 to 250 mg,
once a day, in the morning.
- Sleep disorder due to working in shifts:
150 mg, once a day, about one hour
before starting the shift.

Do not exceed the recommended dose.

Crushing/halving/chewing

Do not halve the tablet in the absence
of a score line; there is no information
regarding crushing or chewing the tablet.

**If you took an overdose, 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 Nuvigil
may include:

- Sleeping difficulties.
- Confusion.
- Being excited.
- Nausea and diarrhea.
- Chest pain.
- Anxiety.
- Restlessness.
- Feeling disoriented.
- Hallucinations (hearing, seeing, or
feeling things that are not really there).
- Fast or slow heartbeat.
- Increased blood pressure.
- Shortness of breath.

Adhere to the treatment as recommended
by the doctor.

Even if there is an improvement in your
health, do not stop treatment with the
medicine without consulting 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 Nuvigil
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 to
the doctor immediately if the following
appear:**

Severe skin rash or severe allergic reaction

- Skin rash, hives, sores in the mouth,
blisters and peeling of the skin.

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

- Swelling of the face, eyes, lips, tongue
or throat.

- Difficulty swallowing, breathing or
hoarseness.

- Fever, shortness of breath, swelling of
the legs, yellowing of the skin or whites
of the eyes, or dark urine.

Mental (psychiatric) symptoms, including:

- Depression.

- Hallucinations (hearing, seeing, or
feeling things that are not really there).

- Suicidal thoughts.

- Other mental problems.

- Feeling anxious.

- An extreme increase in activity and
talking (mania).

- Aggressive behavior.

Effects that indicate a heart problem,
including chest pain, irregular heartbeat
and breathing difficulties.

The most common side effects include:

- Headache.

- Dizziness.

- Nausea.

- Sleeping difficulties.

Some of the effects of Nuvigil 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 the
preparation.

**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.

For bottle packages only: after first
opening the bottle, the medicine can
be used for 24 months from the date of
opening, but no later than the expiry date
of the preparation.

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:**

Nuvigil 50 mg: a round, white to off-white
tablet, debossed with [teva] on one side and
with the number "205" on the other side.

Nuvigil 150 mg: an oval-shaped, white
to off-white tablet, debossed with [teva] on
one side and with the number "215" on
the other side.

Nuvigil 250 mg: an oval-shaped, white
to off-white tablet, debossed with [teva] on
one side and with the number "225" on
the other side.

Each package contains 7, 28, 30 or 60
tablets packaged in bottles or blisters.
Not all package types and sizes may be
marketed.

Name of License Holder and its Address
Abic Marketing Ltd., P.O.B. 8077, Netanya.

Name of Manufacturer and its Address
Teva Pharmaceutical Industries Ltd.,
P.O.B. 3190, Petah-Tikva.

This leaflet was checked and approved by
the Ministry of Health in December 2019.

Registration numbers of the medicine in
the National Drug Registry of the Ministry
of Health:

Nuvigil 50 mg: 155.83.34388

Nuvigil 150 mg: 155.84.34389

Nuvigil 250 mg: 155.85.34390

teva

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