

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Quviviq 25 mg Quviviq 50 mg Film-coated tablets

The active ingredient and its quantity:

Daridorexant (as hydrochloride) 25 mg

Daridorexant (as hydrochloride) 50 mg

Inactive ingredients and allergens in the preparation: for a list of inactive ingredients and allergens in the preparation – see section 6.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

This medicine is intended for the treatment of adults with insomnia, when symptoms persist for at least 3 months and significantly impair daytime functioning.

Therapeutic class: orexin receptor antagonists, psycholeptics.

Quviviq contains the active ingredient daridorexant, which belongs to the class of medicines called orexin receptor antagonists.

Orexin is a substance produced in the brain, which contributes to wakefulness. Blocking the action of orexin with the medicine helps you fall asleep faster, sleep continuously for a longer period of time, and improves your ability to function normally during the day.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional components the medicine contains.
 - You have narcolepsy – a condition that causes you to suddenly and unexpectedly fall asleep at any time.
 - You are taking medicines that may increase the levels of the medicine in the blood, such as:
 - Oral medicines for treatment of fungal infections, such as: ketoconazole, posaconazole, voriconazole, itraconazole.
 - Certain medicines for treatment of bacterial infections (antibiotics), such as: clarithromycin, josamycin, telithromycin, troleandomycin.
 - Certain medicines for treatment of HIV infection, such as: ritonavir, elvitegravir, indinavir, saquinavir, telaprevir, danoprevir, lopinavir, nelfinavir, boceprevir.
 - Certain medicines for treatment of cancer: ceritinib, idelalisib, ribociclib, tucatinib.
- Ask your doctor whether the medicine you are taking prevents you from using Quviviq.

Special warnings regarding the use of the medicine

Before treatment with the medicine, tell the doctor if:

- You have depression, have or have previously had suicidal thoughts
- You have a psychiatric disorder
- You are currently taking medicines that affect the brain, such as treatments for anxiety or depression
- You have regularly taken drugs (that are not medicines) in the past or been addicted to drugs or alcohol
- You have liver problems: depending on their severity, the medicine may not be recommended for you or a lower dose might be required
- You have breathing difficulties such as severe chronic obstructive pulmonary disease (COPD)
- You have a history of falling and are older than 65 (since there is generally a higher risk of falling in patients above this age).

Your doctor may want to monitor how the medicine affects you.

Refer to your doctor if the following side effects occur during treatment with the medicine:

- Sleep paralysis – a temporary inability to move or talk for several minutes upon falling asleep or awakening.
- Hallucinations – seeing or hearing vivid or disturbing things that are not real upon falling asleep or awakening.

If you have depression and your condition worsens or if thoughts of harming yourself appear, refer to the doctor immediately.

Children and adolescents:

There is no information regarding the efficacy and safety of Quviviq in children and adolescents under the age of 18. Do not use Quviviq in children and adolescents 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 the pharmacist. Especially if you are taking:

- Certain antibiotic medicines (erythromycin, ciprofloxacin, clarithromycin, rifampicin), medicines that suppress the immune system (cyclosporine), antifungal medicines (itraconazole), anti-cancer medicines (ceritinib), medicines for treatment of HIV (ritonavir, efavirenz). These medicines may increase or decrease the levels of Quviviq in the blood. Some of these medicines are even contraindicated with Quviviq (see section 2 "Do not use this medicine if"). Your doctor will instruct you on this matter.
- Certain medicines that work on the brain (such as: diazepam, alprazolam) may interact with Quviviq. Your doctor will instruct you on this matter.

- Certain medicines to treat blood coagulation disorder (such as: dabigatran) may interact with Quviviq; therefore, precautions may be required. Your doctor will instruct you on this matter.
- Certain medicines to treat cardiac function disorder (such as: digoxin) may interact with Quviviq; therefore, precautions may be required. Your doctor will instruct you on this matter.

Use of the medicine and food

Avoid eating grapefruit or drinking grapefruit juice in the evening, as they may increase the levels of the medicine in the blood.

Use of the medicine and alcohol consumption

Drinking alcohol during treatment with the medicine may increase the risk of impaired balance and coordination.

Pregnancy, breastfeeding and fertility

Pregnancy

No information is available regarding the use of daridorexant in pregnant women. Therefore, Quviviq should be used during pregnancy only if your condition necessitates treatment with daridorexant. If you are pregnant, breastfeeding, think you may be pregnant or are planning to become pregnant – consult your doctor before using this medicine. It is unknown whether Quviviq might harm the fetus.

Breastfeeding

A small amount of Quviviq passes into breast milk. A risk of excessive somnolence in the breastfed baby cannot be ruled out.

Consult with the doctor regarding the most appropriate way to feed your baby during treatment with Quviviq, or alternatively, stop/avoid treatment with the preparation, while taking into account the benefit of breastfeeding for the child and the benefit of treatment for the nursing woman.

Fertility

It is not known whether Quviviq affects human fertility.

Driving and operating machinery

Do not drive or operate dangerous machinery while using the medicine.

Hypnotics have a significant effect on the ability to drive and operate machinery.

It is recommended to wait at least about 9 hours between taking Quviviq and driving or using machinery.

Be cautious while driving or using machinery in the morning after taking Quviviq.

Do not engage in potentially hazardous activities if you are not sure that you are fully alert, especially during the first days of treatment.

Important information about some of the ingredients of the medicine

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

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined by the doctor only. The generally accepted dosage is one tablet of Quviviq 50 mg before bedtime.

Method of administration:

Take the medicine once a day, by mouth, in the half hour before bedtime at night.

The medicine may be taken with or without food; however, if it is taken with or immediately after a large meal, it may start to work later.

Special populations:

If you have liver problems or if you are taking certain medicines, the doctor may prescribe you a reduced dose of one 25 mg Quviviq tablet per day before bedtime.

Duration of treatment:

The duration of treatment should be as short as possible.

The appropriateness of continued treatment will be assessed by the doctor within 3 months of treatment and periodically thereafter.

Do not exceed the recommended dose.

If you take an overdose or a child swallows this medicine by mistake, go to the doctor or to a hospital emergency room and take the package of the medicine with you. The possible side effects in case of an overdose are: excessive sleepiness and muscle weakness.

If you forget to take this medicine at the appointed time, do not take the medicine later during the night, otherwise you may feel drowsy in the morning. Do not take a double dose to compensate for a forgotten tablet. Take the next dose at the usual time. Follow the treatment as recommended by the doctor.

You may stop taking the medicine without a need to gradually reduce the dose, and without harmful effects.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, use of this medicine may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not experience any of them.

Common side effects – effects that occur in up to 1 out of 10 users:

- Headache
- Excessive sleepiness
- Dizziness
- Tiredness
- Feeling nausea

Uncommon side effects – effects that occur in up to 1 out of 100 users:

- Temporary inability to move or talk (sleep paralysis) for several minutes upon falling asleep or awakening (see section 2)
- Seeing or hearing vivid or disturbing things that are not real (hallucinations, see section 2)

- Allergic reactions (including rash, hives [urticaria])
- Unusual dreams, nightmares
- Sleep-walking

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link:

<https://sideeffects.health.gov.il/>

5. Storage conditions

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton package.
- Store below 25°C.
- Do not discard the medicine in the wastewater or domestic waste. Ask the pharmacist how to dispose of a medicine that you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Tablet cores: Mannitol, microcrystalline cellulose, povidone, croscarmellose sodium, silicon dioxide, magnesium stearate.

Film coating: Hypromellose, titanium dioxide, microcrystalline cellulose, talc, glycerol, iron oxide red, iron oxide black, iron oxide yellow (50 mg tablets only).

• What does the medicine look like and what are the contents of the package?

Quviviq 25 mg film-coated tablets

Light purple, triangular tablet, with the number 25 on one side and "i" on the other side.

Quviviq 50 mg film-coated tablets

Light orange, triangular tablet, with the number 50 on one side and "i" on the other side.

The tablets are supplied in a carton package containing 10, 20 or 30 film-coated tablets in a blister pack. Not all package sizes may be marketed.

• License holder and the address: CTS Ltd., 4 Haharash St., Hod Hasharon, Israel

• Name and address of the manufacturer:
Idorsia Pharmaceuticals Ltd. (Switzerland)
Hegenheimermatweg 91, 4123 Allschwil, Switzerland

• Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
181-50-38547-99
181-51-38548-99

This leaflet was checked and approved by the Ministry of Health in 01/2026