

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section “Possible side effects” for how to report side effects.

Patient Information

Read this leaflet carefully before taking or using the medicine. This medicine has been personally prescribed to you and you may not pass it on to anyone else. Even if they have the same symptoms of the disease as you, the medicine could harm them.

Keep the package leaflet, you may want to read it again later.

QUVIVIQ film-coated tablets

What is QUVIVIQ and when is it used?

Prescribed by your doctor.

QUVIVIQ is to treat sleeping disorders (insomnia) in adults.

QUVIVIQ contains the active substance called daridorexant, which belongs to the class of medicines called “orexin receptor antagonists”.

Orexin is a substance produced by the brain that keeps you awake. By blocking the action of orexin, QUVIVIQ enables you to fall asleep faster and stay asleep longer.

When should QUVIVIQ not be taken?

If you are allergic to the active substance daridorexant, or any of the other ingredients of this medicine (see What does QUVIVIQ contain?).

If you have narcolepsy, a condition that causes you to suddenly and unexpectedly fall asleep at any time.

If you are taking medicines which may increase the levels of QUVIVIQ in your blood, such as:

- oral medicines to treat fungal infections, such as ketoconazole, posaconazole, voriconazole, itraconazole
- certain medicines to treat bacterial infections, such as the antibiotics clarithromycin, josamycin, telithromycin, troleandomycin
- certain medicines to treat HIV infection, such as ritonavir, elvitegravir, indinavir, saquinavir, telaprevir, danoprevir, lopinavir, nelfinavir, boceprevir
- certain medicines used to treat cancer, such as ceritinib, idelalisib, ribociclib, tucatinib.

Ask your doctor if the medicine you are taking prevents you from taking QUVIVIQ.

When is caution necessary when taking QUVIVIQ?

Talk to your doctor or pharmacist before taking QUVIVIQ if you:

- have depression or have or ever had suicidal thoughts
- have a psychiatric or neurological disorder
- currently take medicinal products that affect your brain such as treatments for anxiety or depression
- use drugs or are/have been addicted to medicines, drugs or alcohol
- have liver problems: depending on their severity, QUVIVIQ may not be recommended, or a lower dose might be required
- have breathing difficulties (such as severe obstructive sleep apnoea or severe chronic obstructive pulmonary disease [COPD])
- have a history of falling and are older than 65 (because there is generally a higher risk of falling in patients > 65).

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

Tell your doctor if you get any of the following side effects while taking QUVIVIQ:

- sleep paralysis: a temporary inability to move or talk for up to several minutes after waking up or before falling asleep
- hallucinations: seeing or hearing vivid or disturbing things that are not real upon awakening or falling asleep
- cataplexy-like symptoms: onset of sudden muscle weakness or paralysis during the day usually in response to a sudden emotional reaction such as anger, fear, joy, laughter or surprise.

If you have depression and you experience a worsening or have thoughts of harming yourself, call your doctor straight away.

There have been reports of people engaging in activities while asleep or not fully awake that they do not remember later, after taking medicines for sleep disorders (including medications similar to QUVIVIQ). The behaviours observed included sleepwalking, sleep-driving, preparing food, eating, using the phone, or having sex. These behaviours may result in injuries to yourself and to others. Stop the treatment immediately and contact your doctor immediately if you experience such behaviour.

This medicine is not for children and adolescents under 18 years of age because QUVIVIQ has not been tested in this age group.

Other medicines and QUVIVIQ

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Certain antibiotics (such as erythromycin, ciprofloxacin, clarithromycin, rifampicin), immuno-suppressants (such as cyclosporine), medicines to treat fungal infections (such as itraconazole), medicines to treat cancer (such as ceritinib), or medicines to treat HIV disease (such as ritonavir, efavirenz) can increase or decrease the levels of QUVIVIQ in the blood. Some of these medicines must not be taken with QUVIVIQ (see also “When should QUVIVIQ not be taken?”). Your doctor will advise you on this.

Certain medicines could interact with QUVIVIQ, including:

- medicines that work in your brain (such as diazepam, alprazolam),
- medicines that lower cholesterol level (such as simvastatin at high doses),
- medicines to treat blood coagulation disorders, such as dabigatran,
- medicines used to treat heart failure, such as digoxin.

In these cases, some precaution is required. Your doctor will advise you on this.

QUVIVIQ with food, drink and alcohol

Drinking alcohol with QUVIVIQ can increase the risk of impaired balance and coordination. Therefore, alcohol should be avoided during treatment with QUVIVIQ.

Avoid consuming grapefruit or grapefruit juice in the evening as they may increase the level of QUVIVIQ in the blood.

Driving and using machines

A period of approximately 9 hours is recommended between taking QUVIVIQ and driving or using machines. Be cautious about driving or using machines in the morning after taking QUVIVIQ. Do not engage in potentially hazardous activities, driving, or operating heavy machinery if you are not sure you are fully alert, especially shortly after waking up in the first few days of treatment.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

Inform your doctor or pharmacist if you suffer from other illnesses, have allergies or are taking other medicines (including those you have bought yourself!).

Can QUVIVIQ be used during pregnancy or breast-feeding?

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

As a precautionary measure, use of the therapy during pregnancy should be avoided. Your doctor will help you decide what is best for you and your child.

It is not known if QUVIVIQ passes into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with QUVIVIQ.

How to take QUVIVIQ?

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

Recommended dose for adults over 18 years of age

The recommended dose is 50 mg of QUVIVIQ once per night.

If you have liver problems or take certain other medicines, your doctor may prescribe you a lower dose of one 25 mg tablet of QUVIVIQ per night.

Your doctor will advise you on the dose of QUVIVIQ to take.

Only take QUVIVIQ orally, one time per night, within 30 minutes before going to bed.

You can take QUVIVIQ with or without food, however it may take longer to work if you take it with or right after a high-fat, high-calorie meal.

Swallow the tablets whole. The tablets should not be broken, chewed or dissolved.

The treatment duration should be as short as possible. The appropriateness of continued treatment will be assessed within 3 months by your doctor and periodically thereafter.

Children and adolescents

The use and safety of QUVIVIQ in children and adolescents under 18 has not yet been tested. QUVIVIQ is not suitable for use in children and adolescents under the age of 18.

If you take more QUVIVIQ than you should

If you take more QUVIVIQ than you should, talk to your doctor straight away.

If you forget to take QUVIVIQ

If you forget to take QUVIVIQ at bedtime, then you should not take the tablet later during the night, otherwise you may feel drowsy in the morning. Do not take a double dose to make up for a forgotten tablet.

If you stop taking QUVIVIQ

Treatment with QUVIVIQ can be stopped without a need to gradually reduce the dose.

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

Do not change the prescribed dosage on your own. If you think that the medicine is too weak or too strong, talk to your doctor or pharmacist.

Possible side effects

Stop taking QUVIVIQ and contact a doctor immediately if you notice any of the following signs of a serious allergic reaction:

- Difficulty breathing with or without swelling of the face, lips, tongue and/or throat
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty swallowing

Common (may affect up to 1 in 10 people):

- headache
- excessive sleepiness
- dizziness
- fatigue
- nausea

Uncommon (may affect up to 1 in 100 people):

- temporary inability to move or talk (sleep paralysis) for up to several minutes while you are going to sleep or waking up
- seeing or hearing vivid or disturbing things that are not real (hallucinations)
- allergic reactions (such as skin-rash, also note the information on severe allergic reactions at the beginning of this section)
- abnormal dreams, nightmares

Contact your doctor immediately if you experience any of these symptoms.

Call your doctor straight away if you have any worsening depression or thoughts of suicide or dying.

If you get any side effects, talk to your doctor or pharmacist. This also applies in particular to side effects that are not listed in this leaflet.

What else should be taken into consideration?

Shelf life

The medicine may only be used up to the date marked "EXP" on the container.

Storage conditions

Do not store above 30°C.

Keep out of reach of children.

Further information

Your doctor or pharmacist can provide you with further information. These people have the detailed information for healthcare professionals.

What does QUVIVIQ contain?

QUVIVIQ 25 mg film-coated tablets are light purple arc-triangle shaped, debossed with '25' on one side, and 'i' on the other side.

QUVIVIQ 50 mg film-coated tablets are light orange arc-triangle shaped, debossed with '50' on one side, and 'i' on the other side.

Active ingredients

Each tablet contains daridorexant hydrochloride, equivalent to 25 mg or 50 mg of daridorexant.

Excipients

Tablet cores: Mannitol, microcrystalline cellulose, povidone K 30, croscarmellose sodium, highly dispersed silicon dioxide, magnesium stearate.

Film coating: Hypromellose, microcrystalline cellulose, glycerol, talc, titanium dioxide (E171), iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172; in 50 mg tablets only).

Marketing authorisation number

68481

Where can you get QUVIVIQ? What packs are available?

In pharmacies, only with a prescription.

QUVIVIQ 25 mg:

Available in packs of 10 film-coated tablets (one blister contains 10 tablets) and in packs of 30 film-coated tablets (3 blisters each containing 10 tablets).

QUVIVIQ 50 mg:

Available in packs of 10 film-coated tablets (one blister contains 10 tablets) and in packs of 30 film-coated tablets (3 blisters each containing 10 tablets).

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