text free area

FPO

QUVIVIQ® 25 mg film-coated tablets
QUVIVIQ® 50 mg film-coated tablets
daridorexant
PAAXXXXXX
362-03_Mockup

FPO

QUVIVIQ® 25 mg film-coated tablets
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PAAXXXXXX
362-03_Mockup

text free area

Scan the QR code for a summary leaflet about your medicine.
This does not replace the package leaflet contained in the pack.
https://qr.codes/T18dxo

Package leaflet: Information for the user

QUVIVIQ® 25 mg film-coated tablets
QUVIVIQ® 50 mg film-coated tablets

daridorexant

▼ This medicine 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 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What QUVIVIQ is and what it is used for

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

QUVIVIQ is to treat insomnia in adults.

How QUVIVIQ works
Orexin is a substance produced by the brain that helps keep you awake. By blocking the action of orexin, QUVIVIQ enables you to fall asleep faster and stay asleep longer, and improves your ability to function normally during the day.

2. What you need to know before you take QUVIVIQ

Do not take QUVIVIQ
- if you are allergic to daridorexant or any of the other ingredients of this medicine (listed in section 6).
- 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 level 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, elvetegravir, indinavir, saquivanir, telaprevir, danoprevir, lopinavir, nelfinavir, boceprevir.
  - certain medicines to treat cancer such as ceritinib, idelasilib, ribociclib, tucatinib.

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

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

- have depression or have or ever had suicidal thoughts
- have a psychiatric disorder
- currently take medicinal products that affect your brain such as treatments for anxiety or depression
- have regularly taken drugs (except as medicines) or been addicted to 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 chronic obstructive pulmonary disease)
- 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 upon awakening or falling asleep
- hallucinations: seeing or hearing vivid or disturbing things that are not real upon awakening or falling asleep

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

Children and adolescents
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 because:

- certain antibiotics (erythromycin, ciprofloxacin, clarithromycin, rifampicin), immuno-suppressants (cyclosporine), antifungal agents (itraconazole), cancer treatments (ceritinib), or HIV treatments (ritonavir, efavirenz) can increase or decrease the level of QUVIVIQ in the blood. Some of these medicines may be contra-indicated with QUVIVIQ (see section "Do not take QUVIVIQ"). Your doctor will advise you on this.
- certain medicines that work in your brain (e.g., diazepam, alprazolam) could interact with QUVIVIQ. Your doctor will advise you on this.
- certain medicines to treat blood coagulation disorder such as dabigatran could interact with QUVIVIQ, which would require some precaution. Your doctor will advise you on this.
- certain medicines to treat cardiac impairment such as digoxin could interact with QUVIVIQ, which would require some precaution. 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.

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

Pregnancy, breast-feeding and fertility
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.

It is not known if QUVIVIQ can harm your unborn baby.

A small amount of QUVIVIQ passes into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with QUVIVIQ.

It is not known if QUVIVIQ affects human fertility.

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 if you are not sure you are fully alert, especially in the first few days of treatment.

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

3. 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.

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

The recommended dose is one 50-mg tablet of QUVIVIQ 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.

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.

- Take QUVIVIQ, one time per night, by mouth, in the half hour before going to bed at night.
- You can take QUVIVIQ with or without food, however it may take longer to work if you take it with or right after a large meal.

If you take more QUVIVIQ than you should
If you take more QUVIVIQ than you should, you may experience excessive sleepiness and muscle weakness. Contact your doctor straight away.

If you forget to take QUVIVIQ
If you forget to take QUVIVIQ at bedtime, then you should not take it 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, and without harmful effects.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people):
- headache
- excessive sleepiness
- dizziness
- tiredness
- feeling sick (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 (see section 2).
- seeing or hearing vivid or disturbing things that are not real (hallucinations; see section 2)
- allergic reactions (including rash, urticaria)
- abnormal dreams, nightmares
- sleepwalking

Please talk to your doctor if any of these happen to you.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store QUVIVIQ

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.
The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer require. These measures will help to protect the environment.

6. Contents of the pack and other information

What QUVIVIQ contains
The active substance is daridorexant.

QUVIVIQ 25 mg film-coated tablets
Each tablet contains daridorexant hydrochloride, equivalent to 25 mg of daridorexant.

QUVIVIQ 50 mg film-coated tablets
Each tablet contains daridorexant hydrochloride, equivalent to 50 mg of daridorexant.

The other ingredients are:
Tablet cores: Mannitol (E421), microcrystalline cellulose (E460), povidone, croscarmellose sodium (see section 2 "QUVIVIQ contains sodium"), silicon dioxide, magnesium stearate.

Film coating: Hypromellose (E464), microcrystalline cellulose (E460), glycerol, talc (E553), titanium dioxide (E171), iron oxide red (E172), iron oxide black (E172), iron oxide yellow (E172; 50 mg tablets only).

What QUVIVIQ looks like and contents of the pack
Film-coated tablet (tablet)

QUVIVIQ 25 mg film-coated tablets
Light purple, triangular tablet with 25 on one side, and 'i' (Idorsia logo) on the other side.

QUVIVIQ 50 mg film-coated tablets
Light orange, triangular tablet with 50 on one side, and 'i' (Idorsia logo) on the other side.

QUVIVIQ is available in blister packs of 10 or 30 film-coated tablets.

Not all pack sizes may be marketed.

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Manufacturer
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This leaflet was last revised in May 2026

Component Details		Date: 04 Aug 2026 Time: 13:49	Colours	
Packaging Plant	Idorsia		Printing	Non-Printing
GLAMS Part Number	362-03		Black	Spec
Comp. Type	Leaflet			
Proof	04			
Spec Nº	ZS: 003000026481			
Market	United Kingdom			
Smallest Font Size	9 pt			
AW Dimensions	593 x 388 mm			
CMO Comp. Code + Prod. Description	PAAXXXXXX - PP INSERT QUVIVIQ 25/50mg UK			
Old CMO Comp. Code	PAA236711			
Pharmacode	PAAXXXXXX			
Barcode Symbology / Type	N/A			
Perigord ID Nº	950459			

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