

PATIENT INFORMATION LEAFLET

Kwells®

300 microgram tablets

Hyoscine Hydrobromide

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Kwells 300 microgram tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you have any unusual effects after taking this medicine, tell your doctor or pharmacist.

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1. WHAT ARE KWELLS® TABLETS AND WHAT ARE THEY USED FOR?

Kwells 300 microgram tablets are used for the fast and effective prevention and control of travel sickness. Travel sickness happens when the brain receives mixed messages. Visual messages from the eyes inform the brain that the immediate surroundings are stationary, but a delicate balancing organ in the ear tells the brain that you are moving. This conflicting information triggers the nausea we associate with travel sickness. The active substance in Kwells tablets is hyoscine hydrobromide. Hyoscine hydrobromide temporarily reduces the effect of movement on the balance organs of the inner ear and the nerves responsible for nausea.

Because Kwells tablets melt in the mouth, absorption into the bloodstream is very rapid and they can be taken up to 20-30 minutes before travelling or at the onset of sickness.

2. BEFORE YOU TAKE KWELLS® TABLETS

DO NOT take Kwells tablets if you:

- Are allergic (hypersensitive) to hyoscine hydrobromide or any of the other ingredients in the tablets (see *Section 6. Further Information*).
- Have any of the following conditions:
 - Glaucoma.
 - Blockage of intestines (Paralytic ileus).
 - Narrowing of the stomach outlet (Pyloric stenosis).
 - Myasthenia gravis.
 - Enlarged prostate gland.

Before taking Kwells tablets, you should see your doctor if you:

- Are over 60 years of age.
- Are under medical care, especially for heart, metabolic, gastrointestinal, liver or kidney conditions.
- Have previously had a sudden painful inability to pass urine.
- Have ulcerative colitis.
- Have diarrhoea or fever.
- Have Down's Syndrome.
- Suffer from seizures or fits.

Additional precautions for children:

This product should only be given to children over 10 years old. Since it may cause drowsiness, children taking this medicine should not be left unattended.

Taking other medicines:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take Kwells tablets if you are taking any of the following medicines, unless advised by your doctor:

- Amantadine (an antiviral).
- Antihistamines.
- Antipsychotics.
- Antidepressants.
- Linezolid (and antibiotic).
- Domperidone and metoclopramide (for nausea and vomiting).
- Sublingual nitrates (for angina).

Taking Kwells tablets with food and drink:

Do not drink alcohol while taking Kwells tablets as this may make you feel more drowsy.

Driving and using machines:

May cause drowsiness. If affected do not drive or operate machinery.

Pregnancy and breast-feeding:

Do not take Kwells tablets if you are pregnant or breast-feeding unless recommended by your doctor or midwife.

3. HOW TO TAKE KWELLS® TABLETS

If Kwells tablets have been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

The tablets can be sucked, chewed or swallowed. They have a scoreline so they can be halved if necessary. The tablets can be taken up to 30 minutes before travelling to prevent travel sickness or at the onset of nausea.

Adults: Take one tablet every 6 hours, as required. Do not take this medicine more than 3 times in 24 hours.

Elderly: Consult your doctor or pharmacist before taking Kwells tablets.

Children over 10 years: Give your child half or one tablet every 6 hours, as required. Do not give your child this medicine more than 3 times in 24 hours. Kwells tablets should not be given to children under 10 years of age.

If you take more Kwells tablets than recommended:

Symptoms of an overdose may include: fast or irregular heart-beat, difficulty passing water, blurred vision or dislike of bright light. Hallucinations may occur.

If you have any of these symptoms or have taken more than the recommended dose, tell your doctor or contact your nearest Accident and Emergency Department immediately.

How to help avoid travel sickness:

- Sit with the head tilted back to stabilise the balancing mechanism in the ear.
- Ensure the vehicle you are in is well ventilated.
- Try to have a clear view of the window.
- Have a bite to eat before the journey to help keep the stomach settled, but avoid greasy food.

- If you travel by car take regular breaks for exercise, fresh air and refreshments.
- In an aeroplane you can ease the pressure on your ears by sucking a boiled sweet during take off and landing.
- NEVER Read.
- Avoid strong smelling food, smoke, perfume, or petrol fumes.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Kwells tablets can cause side effects, although not everybody gets them.

Some people have experienced blurred vision, dilated pupils, dry mouth, drowsiness and dizziness. You may also experience an increased body temperature due to decreased sweating.

Less frequently, there have been reports of restlessness, hallucinations and confusion. If you are epileptic, you might suffer from increased seizure frequency.

As with all medicines, some people may be allergic to the tablets. If you are allergic, you may experience difficulty in breathing, coughing, wheezing or symptoms such as rash, itching and swelling.

If you experience any of these effects or react badly to the tablets in any other way, tell your doctor immediately.

5. HOW TO STORE KWELLS® TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C. This product should be stored in the original carton.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Kwells tablets contain:

- The **active substance** is hyoscine hydrobromide at a strength of 300 micrograms.
- The **other ingredients** are mannitol (E421), potato starch, gelatine powder, aluminium stearate, saccharin sodium (E954) and ferric oxide (E172).

What Kwells tablets look like and contents of the pack:

Kwells tablets are small, circular, pink and flat with a single scoreline on the surface. The carton contains 12 tablets packaged inside a blister pack.

Marketing Authorisation Holder:

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