

Kwells[®] Kids
150 microgram tablets
Hyoscine Hydrobromide

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

This medicine is available without prescription. However, you still need to take Kwells Kids 150 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 child's symptoms worsen or do not improve.
- If your child has any unusual effects after taking this medicine, tell your doctor or pharmacist.

IN THIS LEAFLET:

1. What are Kwells Kids tablets and what are they used for?
2. Before you give Kwells Kids tablets to your child
3. How to take Kwells Kids tablets
4. Possible side effects
5. How to store Kwells Kids tablets
6. Further information

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

Kwells Kids 150 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 Kids 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 Kids 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 GIVE KWELLS KIDS TABLETS TO YOUR CHILD

DO NOT give Kwells Kids tablets to your child if he or she:

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

Before giving Kwells Kids tablets to your child, you should see your doctor if he or she:

- Is under medical care, especially for heart, metabolic, gastrointestinal, liver or kidney conditions.
- Has previously had a sudden painful inability to pass urine.
- Has ulcerative colitis.
- Has diarrhoea or fever.
- Has Down's Syndrome.
- Suffers from seizures or fits.

Additional precautions:

This product should only be given to children over 4 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 your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Do not give Kwells Kids tablets to your child if he or she is taking any of the following medicines, unless advised by your doctor:

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

Taking Kwells Kids tablets with food and drink:

Do not drink alcohol while taking Kwells Kids 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 Kids tablets if you are pregnant or breast-feeding unless recommended by your doctor or midwife.

Important information about some of the ingredients:

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

3. HOW TO TAKE KWELLS KIDS TABLETS

If Kwells Kids tablets has been prescribed for your child by a 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 even at the onset of nausea.

Children over 10 years: Give your child one or two tablets every 6 hours, as required. Do not give your child this medicine more than 3 times in 24 hours.

Children 4 to 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 Kids tablets should not be given to children under 4 years of age.

If your child takes more Kwells Kids 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 your child has any of these symptoms or has 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 Kids tablets can cause side effects, although not everybody gets them.

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

Less frequently, there have been reports of restlessness, hallucinations and confusion.

If your child is epileptic, he or she might suffer from increased seizure frequency.

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

If your child experiences any of these effects or reacts badly to the tablets in any other way, tell your doctor immediately.

Reporting of side effects

If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 KWELLS KIDS TABLETS

Keep out of the sight and reach 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 Kids tablets contain:

- The **active substance** is hyoscine hydrobromide at a strength of 150 micrograms.
- The **other ingredients** are mannitol (E421), potato starch, gelatine powder, aluminium stearate, and saccharin sodium (E954).

What Kwells Kids tablets look like and contents of the pack:

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

Marketing Authorisation Holder:

Dexcel[®] - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK

Manufacturer:

Dexcel[®] - Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK

Doppel Farmaceutici S.r.l. Italy, Via Volturno, 48-20089, Quinto de'Stampi, Rozzano (Milano), Italy

This leaflet was last revised in June 2023.

Remember: If you have any doubts about using Kwells Kids correctly, seek the advice of your doctor or pharmacist.