SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Kwells 300 microgram tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hyoscine Hydrobromide 300 microgram

For excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Small pink circular, flat faced tablets with bevelled edges. One face is bisected by a score line and the other is plain.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prevention of travel sickness.

4.2 Posology and method of administration

Tablets to be sucked, chewed or swallowed.

Adults:
1 tablet every 6 hours if required. Do not take more than 3 tablets in 24 hours.

Elderly:
There is no special dosage regimen for the elderly and as such caution should be exercised

Children:
Children over 10: ½-1 tablet every 6 hours if required. Do not take more than 1½-3 tablets in 24 hours.

Tablets to be taken up to 30 minutes before the start of the journey to prevent travel sickness, or at the onset of nausea.

4.3 Contraindications

Prostatic enlargement, paralytic ileus, pyloric stenosis, glaucoma and myasthenia gravis.

In addition, Kwells should not be given to patients with a known sensitivity to hyoscine hydrobromide or any other component of the product.

4.4 Special warnings and precautions for use

The elderly and patients under medical care (in particular those at risk of acute urinary retention, or with cardiovascular, metabolic, gastrointestinal, liver or renal disease, or suffering from CNS disorders such as seizures) should consult a doctor before taking this product.

In patients with ulcerative colitis its use may lead to ileus or megacolon.

Antimuscarinics should be used with caution in persons with Down's Syndrome.

Caution is advisable in patients with diarrhoea.

Hyperthermia can occur at high ambient temperatures due to decreased sweating, therefore, Kwells should be used with caution in patients with fever.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of hyoscine may be enhanced by other drugs with anticholinergic properties (including amantadine, some antihistamines, phenothiazine antipsychotics and tricyclic antidepressants), therefore, combining these drugs with hyoscine should be avoided.

There may be an increased risk of side effects when given with MAOIs due to inhibition of drug-metabolising enzymes.

The sedative effect of Kwells may be enhanced with alcohol or CNS depressants.

The reduction in gastric motility caused by Kwells may also affect the absorption of other drugs. There is an antagonism of effect of domperidone and metoclopramide on gastro-intestinal activity.

There could be a reduced effect of sublingual nitrate tablets due to the failure to dissolve properly under the tongue owing to dry mouth.

4.6 Fertility, pregnancy and lactation

The safety of this medicine in pregnancy has not been established. It should only be used during pregnancy, particularly in the first trimester, if the expected benefit to the mother outweighs any potential risk to the developing foetus.

Caution is required during lactation as small amounts of this medicine may pass into breast milk.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The listed adverse drug reactions are based on spontaneous reports, thus an organization according to CIOMS II categories of frequency is not pertinent.

General: hyperthermia at high temperatures due to decreased sweating.

Eye disorders: blurred vision, mydriasis.

Gastrointestinal disorders: dry mouth.

Immune system disorders: allergic reaction and anaphylactic reaction. Hypersensitivity reactions with respective laboratory and clinical manifestations, including asthma syndrome, mild to moderate reactions affecting skin, respiratory tract, gastrointestinal tract, and cardiovascular system, and symptoms such as rash, urticaria, oedema, pruritus, cardio-respiratory distress, have been reported.

Nervous system disorders: drowsiness, dizziness, sedation and somnolence are commonly reported. Central nervous system stimulation including restlessness, hallucinations and confusion, have been less frequently reported following the administration of hyoscine.
There have been rare reports of an increase in seizure frequency in epileptic patients (the same caution for this patient population is included in Section 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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.

4.9 Overdose

The symptoms of overdosage are tachycardia, arrhythmia, blurring of vision and photophobia, urinary retention. Drowsiness is usual but paradoxical stimulation with hallucinations may occur. Treatment: gastric lavage or induced emesis and symptomatic treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hyoscine hydrobromide is thought to act as an anticholinergic agent by both cutting off stimuli to the vestibular apparatus and also by acting directly on the vomiting centre.

5.2 Pharmacokinetic properties

Hyoscine hydrobromide is readily absorbed from the gastro-intestinal tract, and in circulation is bound to plasma proteins. Clinical studies have shown that oral hyoscine hydrobromide is effective in preventing motion sickness at plasma concentration of 50pg/ml (equivalent to 0.17nmol/l). This concentration is reached within 30 minutes following oral/buccal administration of 0.3 mg hyoscine hydrobromide and it is effective for about 4 hours. Hyoscine hydrobromide is almost entirely metabolised in the body.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Potato Starch
Gelatin Powder
Aluminium Stearate
Saccharin Sodium
Ferric Oxide
Purified Water (not detectable)

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs made up of 250µm opaque white PVC coated with 40 gsm PVDC and 20µm hard tempered aluminium foil.

a. Two strips of six tablets in cardboard carton.
b. One strip of twelve tablets in cardboard carton
c. Strip of two tablets stapled into a cardboard carton.
   Pack sizes: 12, 2.

6.6 Special precautions for disposal

No special precautions necessary.

7 MARKETING AUTHORISATION HOLDER

Dexcel®-Pharma Ltd.,
2nd Floor, Bourn, 1 Manor House Drive, Coventry, CV1 2FX, United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 14017/0299

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/10/2005

10 DATE OF REVISION OF THE TEXT

16/12/2025