Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kwells 300 microgram Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hyoscine Hydrobromide 300 microgram

Excipient(s) with know effect
This product contains sodium (as saccharin sodium), please see section 4.4 for further information.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet
Small, circular, pink, flat tablet with bevelled edges and a single scoreline on the surface.
The scoreline is to allow breaking of the tablet into 2 for dosage purposes and ease of swallowing only.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the prevention of motion sickness.

4.2 Posology and method of administration

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

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.
Children under 10: not to be given.

4.3 Contraindications

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

Known hypersensitivity to hyoscine hydrobromide or any other ingredient in 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.

May cause drowsiness. Children taking this medicine should not be left unattended.

Avoid alcoholic drink.

In patients with hepatic impairment an increase of the bioavailability of scopolamine hydrobromide could theoretically occur as hepatic metabolism appears to be the primary route of metabolism. In theory, this could lead to a greater potential for, or prolongation of, undesirable effects.

Kwells 300 microgram tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essesntially 'sodium- free'.

4.5 Interaction with other medicinal products and other forms of interactions

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 failure to dissolve properly under the tongue owing to dry mouth.

In a study in healthy volunteers, the administration of hyoscine with grapefruit juice,an inhibitor of CYP3A, increased the AUC_{0-24h} and prolonged the time to peak concentration, resulting in a higher drug bioavailability.

4.6 Fertility, pregnancy and lactation

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

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

This product may cause drowsiness and patients receiving it should not drive or operate machinery unless it has been shown that their physical and mental capacity remains unaffected.

4.8 Undesirable effects

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

General: hyperthermia at high temperatures due to decreased sweating.

Eye disorders: blured 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, has been less frequently reported following the administration of hyoscine hydrobromide. 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 HPRA Pharmacovigilance; Website: www.hpra.ie

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. Overdosage (relative or absolute) may also produce flushing, dilated pupils, and symptoms of CNS stimulation.
Treatment: gastric lavage or induced emesis and symptomatic treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiemetics and antinauseants, scopolamine
ATC code: A04 AD01

Hyoscine hydrobromide competitively inhibits muscarinic receptors for acetylcholine and acts as a nonselective muscarinic antagonist, producing both peripheral antimuscarinic properties and central sedative, antiemetic, and amnestic effects.

5.2 Pharmacokinetic properties

Hyoscine hydrobromide is absorbed rapidly, but variably and incompletely from the gastrointestinal tract. The mean time to peak drug concentration is approximately 24 mintues following administration. The oral bioavailability has been reported to be only 13%. Pharmacological effects on the GI tract (decreased motility and decreased gastric secretion), and intestinal metabolism (see below) may also contribute to the limited oral bioavailability. Approximately 30% of hyoscine in the plasma is bound to protein. The elimination half life is estimated at approximately 1 hour.

Limited human data regarding the metabolism of hyoscine are available, however, since only a small proportion (2.6%) of pharmacologically active drug is excreted in the urine, a first pass metabolism is theorized. While the metabolic profile has not been fully elucidated, it is suggested that glucuronide and/or sulfate conjugation are significant metabolic pathways. In addition, it appears that oxidative demethylation of the drug via CYP3A, probably occuring in the intestinal mucosa, is also involved.

5.3 Preclinical safety data

Non-clinical studies reveal no unexpected clinically relevant findings and no evidence of carcinogenicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)
Potato Starch
Gelatine Powder
Aluminium Stearate

Saccharin Sodium (E954)
Ferric Oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25 ^{o}C.

6.5 Nature and contents of container

Blister packs formed from 20µm hard-tempered aluminium foil and 250µm opaque, white PVC/PVDC.
Pack size: 12 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Dexcel Pharma GmbH
Carl-Zeiss-Strasse 2
63755 Alzenau
Germany

8 MARKETING AUTHORISATION NUMBER

PA2261/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2009

10 DATE OF REVISION OF THE TEXT

September 2020