IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0021/070/001
Case No: 2048521

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Bayer PLC

Bayer House, **Strawberry Hill**, **Newbury**, **Berkshire RG14 1JA**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Junior Kwells 150 microgram Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **03/04/2008** until **19/04/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Junior Kwells 150 microgram Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hyoscine Hydrobromide 150 micrograms.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet
Small, circular, white, flat tablet with bevelled edges and a single scoreline on the surface.

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:
Not applicable.

Elderly persons:
Not applicable.

Children:
Children over 10: 1-2 tablets every 6 hours if required.
Do not take more than 3-6 tablets in 24 hours.

Children 4-10: ½-1 tablet every 6 hours if required.
Do not take more than 1½-3 tablets in 24 hours.

Not recommended for children under 4 years except on medical advice.

4.3 Contraindications

Known hypersensitivity to hyoscine hydrobromide or any other component of the product.

Patients suffering from glaucoma.

4.4 Special warnings and precautions for use

The elderly and patients under medical care (in particular those with 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. May cause drowsiness. Children taking this medicine should not be left unattended. Avoid alocoholic drink.

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.

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.

4.6 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

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, has been less frequently reported following the administration of hyoscine hydrobromide.

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 minutes 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 sulphate conjugation are significant metabolic pathways. In addition, it appears that oxidative demethylation of the drug via CYP3A, probably occurring in the intestinal mucosa, is also involved. In a study in healthy volunteers, the administration of hyoscine with grapefruit juice, an inhibitor of CYP3A, increased $AUC_{0\text{-}24h}$ and prolonged the time to peak concentration, resulting in a higher drug bioavailability.

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
Gelatin Powder
Aluminium Stearate
Saccharin Sodium (E954)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 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 20 um hard-tempered aluminium foil and 250um opaque, white PVC.

Pack sizes: 12.

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

Bayer plc
Bayer House
Strawberry Hill
Newbury
Berkshire
RG14 1JA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 21/70/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 April 1989

Date of last renewal: 20 April 2004

10 DATE OF REVISION OF THE TEXT

April 2008