SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Travel Calm Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	micrograms/tablet
Hyoscine hydrobromide	300
Excipient(s) with known effect	mg/tablet
Glucose	276.7

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the prevention and relief of travel sickness.

4.2. Posology and Method of Administration

Adults and children over 12 years: One tablet.

Children 7 to 12 years: Half a tablet.

Children 3 to 7 years: Quarter of a tablet.

Not to be taken by children under 3 years.

Elderly: The normal adult dose is still appropriate in the elderly.

The dose should be taken 20 minutes before the journey and may be repeated in 6-8 hours if necessary.

Not more than three doses to be taken in 24 hours.

For oral administration.

4.3. Contra-Indications

Prostatic enlargement, paralytic ileus, pyloric stenosis, closed angle glaucoma.

4.4 Special warnings and precautions for use

Should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis and cardiac failure. Should be used with caution by elderly patients and in patients suffering from impaired renal, hepatic or metabolic function.

Warning: May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink.

There have been rare reports of an increase in frequency of seizures in epileptic patients.

Not more than three doses to be taken in 24 hours.

Keep all medicines out of the reach of children.

This medicine contains dextrose monohydrate, also known as glucose. Patients with rare glucose-galactose malabsorption should not take this medicine.

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, butyrophenones, phenothiazines and tricyclic antidepressants. Patients should also avoid alcohol. The reduction in gastric motility caused by hyoscine may also affect the absorption of other drugs.

4.6. Pregnancy and Lactation

The safety of hyoscine during pregnancy and lactation has not been established, although there is no definite evidence of adverse consequences if taken during early pregnancy. No significant quantities of hyoscine were

found in milk when the drug was given to lactating women. Nevertheless, the product should not be used during pregnancy, unless the expected benefit is thought to outweigh any possible risk to the foetus.

4.7. Effects on Ability to Drive and Use Machines

Hyoscine may cause drowsiness and dulling of mental alertness and therefore those taking this medication should not take charge of motor vehicles or operate machinery.

4.8 Undesirable effects

Side effects may include drowsiness, dryness of the mouth, thirst, reduced bronchial secretions, mydriasis, loss of accommodation, photophobia, increased intra-ocular pressure, flushing, dry skin, bradycardia followed by tachycardia, with palpitations and arrhythmias, difficulty in micturition, reduction in tone and motility of the gastrointestinal tract leading to constipation. Occasionally vomiting, giddiness and staggering may occur. There have also been occasional reports of confused states and hallucinations when given to children.

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 by searching for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Symptoms of overdo sage may include any of the undesirable effects mentioned above under section 4.8 and tachycardia, rapid or stertorous respiration, hyperpyrexia, restlessness, confusion and excitement, hallucinations and delirium. In severe cases, depression of the central nervous system may occur with coma, circulatory and respiratory failure and death.

Treatment consists of emptying the stomach by lavage and aspiration. Charcoal may be used to prevent further absorption. Give a saline purgative, such as sodium sulphate 30g in 250ml of water.

Peripheral anticholinergic effects may be controlled by the administration of the antichlolinesterase, neostigmine. Excitement may be controlled by diazepam. Otherwise treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Hyoscine is an anticholinergic agent with central and peripheral actions.

5.2. Pharmacokinetic Properties

Hyoscine hydrobromide is readily absorbed from the gastrointestinal tract. It Is almost entirely metabolised, probably in the liver. Only a small proportion of an oral dose is excreted unchanged in the urine. Hyoscine crosses the placental barrier and traces may appear in milk.

5.3. Pre-clinical Safety Data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Dextrose monohydrate
Purified water
Stearic acid
Magnesium stearate

6.2. Incompatibilities

Not applicable.

6.3. Shelf-Life

36 months.

6.4 Special precautions for storage

Do not store above 30°C.

6.5. Nature and Content of Container

PVC blister tray heat-sealed to hard temper aluminium foil containing 12 tablets.

6.6. Instructions for Use, Handling and Disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham
NG2 3AA

8. MARKETING AUTHORISATION NUMBER(S)

PL 00014/5369R

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

15 June 1990

10 DATE OF REVISION OF THE TEXT

17/07/2024