SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Joy-rides Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituent
Hyoscine hydrobromide 0.15 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A raspberry flavoured chewed tablet for oral administration.

4. Clinical Particulars

4.1. Therapeutic Indications

Anti-muscarinic. For the prevention of motion sickness.

4.2. Posology and Method of Administration

Route of administration: Oral.

Adults over 13 years:	2 tablets 20 minutes before start of the journey. Maximum 4 tablets in 24 hours.
Children:	20 minutes before journey. 7 - 12 years: 1 -2 tablets. 4 - 7 years: 1 tablet. Maximum 2 tablets in 24 hours. 3 – 4 years: half a tablet. Maximum 1 tablet in 24 hours. Not recommended under 3 years except on medical advice.

Ideally taken 20 minutes before the start of the journey. However, still effective if taken at onset of nausea or after the journey has begun.

4.3. Contra-indications

Glaucoma.

4.4. Special Warnings and Special Precautions for Use

Do not exceed the stated dose. Avoid alcoholic drink.

If you are epileptic, you might suffer from increased seizure frequency.

4.5. Interactions with other Medicaments and other forms of Interaction

The actions of hyoscine hydrobromide may be potentiated by concurrent phenothiazines, tricyclic antidepressants or alcohol. Aluminium hydroxide preparations may reduce absorption of hyoscine hydrobromide. The actions of tricyclic antidepressants may be potentiated by concurrent hyoscine hydrobromide.

4.6. Pregnancy and Lactation

Safety in pregnancy has not been established, but the drug has been used widely for many years without apparent ill effect. However, the normal precautions of avoiding unnecessary medication especially in the first trimester of pregnancy should be observed.

Hyoscine hydrobromide can cross the placenta and appears in trace quantities in 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

Some patients may experience cholinergic signs and symptoms such as dry mouth, dizziness, blurred vision, dilatation of the pupils with loss of accommodation, photophobia, closed angle glaucoma (very rare), urinary disturbances (urinary emergency and retention), reduced bronchial secretions, transient bradycardia (followed by tachycardia, palpitation and arrhythmias), flushing and dryness of the skin, constipation, nausea and vomiting.

Other signs and symptoms may include hallucination, high temperature (due to decreased sweating) and confusion. These may occur in all patient groups although certain populations (children and the elderly) are more susceptible to anticholinergic toxicity.

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 main symptoms are sleepiness, dry mouth, rapid heart rate, palpitation, dilated pupils. Other signs and symptoms may include hallucination, high

temperature and confusion. These may occur in all patient groups although certain populations (children and the elderly) are more susceptible of anticholinergic toxicity. Take measures to limit intestinal absorption immediately. Parasympathetic agents such as physostigmine should be used as necessary. Do not use phenothiazines.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

The Atropine like actions of hyoscine hydrobromide are well known. The site of action in preventing motion sickness is thought to be either on the cortex or more peripherally on the vestibular apparatus.

5.2. Pharmacokinetic Properties

Hyoscine is rapidly absorbed from the gastro-intestinal tract. About 1 % of an oral dose is eliminated as such in the urine. Traces are found in various secretions, including milk.

5.3. Preclinical Safety Data

None.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Mannitol
Erythrosine (E.127) Lake
Povidone
Raspberry Flavour Trusil J7551
Microcrystalline cellulose
Magnesium stearate

6.2. Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4. Special Precautions for Storage

Store below 25°C in a dry place.

6.5. Nature and Contents of Container

Blister strips consisting of two layers of soft aluminium foil/polyethylene or PVC/PVdC/aluminium foil.
Pack size: 12 tablets

6.6. Instruction for Use/Handling

None.

7. MARKETING AUTHORISATION HOLDER

Teva UK Limited,
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 00289/2263

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

First granted 22 July 1973.
Last renewed 12 April 1996.

10 DATE OF REVISION OF THE TEXT

27/11/2020