SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hyoscine Injection BP 400mcg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hyoscine hydrobromide EP 0.04% w/v

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Solution for Injection

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Due to its anticholinergic activity, hyoscine injection is used as a preoperative medication to control bronchial, nasal pharyngeal and salivary secretions, to prevent bronchospasms and laryngospasm and to block cardiac vagal inhibiting reflexes during induction of anaesthesia and intubation.

4.2 Posology and method of administration

Adults: For pre-medication a dose of 200 to 600 micrograms is given by the subcutaneous or intramuscular route 30 to 60 minutes before induction of anaesthesia.

The injection may if required also be given by the intravenous route for acute use.

Children: A dose of 15mcg/kg is recommended in children.

Elderly: Hyoscine is not recommended for use in the elderly.

4.3 Contraindications

Porphyria; hypersensitivity to hyoscine; narrow angle glaucoma.

4.4 Special warnings and precautions for use

Caution is necessary in treating patients with cardiovascular disease, gastrointestinal obstruction, paralytic ileus, prostatic enlargement, Down's Syndrome, myasthenia gravis, renal or hepatic impairment.

Because hyoscine may cause drowsiness, patients must not drive or operate machinery. Patients should avoid alcohol.

Heat prostration can occur, at high ambient temperatures due to decreased sweating.

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

4.5 Interaction with other medicinal products and other forms of interaction

The antimuscarinic side-effect can be increased by concomitant administration of disopyramide, tricyclic and MAOI drugs, antihistamines, phenothiazines, amantadine and alcohol. Reduced effect of sub-lingual nitrates.

4.6 Fertility, Pregnancy and lactation

Use of hyoscine during pregnancy may cause respiratory depression in the neonate, and should only be given during pregnancy when the potential benefit clearly outweighs the foetal hazard.

4.7 Effects on ability to drive and use machines

Because hyoscine may cause drowsiness, patients must not drive or operate machinery.

4.8 Undesirable effects

The most common side effects are drowsiness, dry mouth, dizziness, blurred vision and difficulty with micturition. Other reported effects include bradycardia, idiosyncratic reactions, mental confusion or excitement, dyspnoea, angioedema, anaphylaxis and anaphylactic shock.

4.9 Overdose

Symptoms of overdose may include dilated pupils, tachycardia, rapid respiration, hyperpyrexia, restlessness, excitement, delirium and hallucinations. In the unlikely event of overdosage, supportive therapy should be implemented. Physostigmine by slow intravenous injection in a dose of 1 to 4mg has been used to reverse the anticholinergic effects, but this drug is rapidly metabolised. Neostigmine by slow intravenous injection in a dose of 0.5 to 2 mg antagonises only the peripheral effects. Diazepam may be given to control excitement.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hyoscine is an anticholinergic drug which inhibits the muscarinic actions of acetylcholine at post ganglionic parasympathetic neuroeffector sites including smooth muscle, secretary glands and CNS sites. Small doses effectively inhibit salivary and bronchial secretions and sweating and provide a degree of amnesia. Hyoscine is a more powerful suppressor of salivation than atropine and usually slows rather than increases heart rate.

5.2 Pharmacokinetic properties

Hyoscine is rapidly absorbed following IV or IM injection and is reversibly bound to plasma protein. Hyoscine is reported to cross the placenta and blood brain barrier. Hyoscine is almost completely metabolised by the liver and excreted in the urine. In one study in man, 3.4% of a single dose, administered by subcutaneous injection was excreted unchanged in urine within 72 hours.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrobromic acid
Sodium hydroxide
Water for Injections

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25ºC and protect from light.

6.5 Nature and contents of container

1ml neutral glass (Type I) ampoules in packs of 5 or 10.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee
Co. Meath
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 35104/0008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Granted: 5 June 1987
Renewed: 17 June 1993
10 November 1998

10 DATE OF REVISION OF THE TEXT

21/03/2014