SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hyoscine Hydrobromide 600 micrograms/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1mg ampoule contains 600 micrograms/ml of hyoscine hydrobromide.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for Injection

A clear colourless solution, practically free from particles.

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 bronchospasm and laryngospasm and to block cardiac vagal inhibiting reflexes during induction of anaesthesia and intubation.

4.2. Posology and method of administration

Dosage

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 15 micrograms/kg is recommended in children.

Elderly

Hyoscine is not recommended for use in the elderly.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Hyoscine should not be administered to patients with myasthenia gravis, megacolon, angle-closure glaucoma, tachycardia, prostatic enlargement with urinary retention, gastrointestinal obstruction, mechanical stenosis in the region of the gastrointestinal tract or paralytic ileus.

Hyoscine should not be given by intramuscular injection to patients being treated with anticoagulant drugs since intramuscular haematoma may occur.

4.4 Special warnings and precautions for use

Caution is necessary in treating patients with cardiovascular disease (e.g. acute myocardial infarction, hypertension and conditions associated with tachycardia (including hyperthyroidism, cardiac insufficiency, and cardiac surgery)), Down's Syndrome, renal or hepatic impairment.
Increased seizure frequency in epileptic patients.

Use in caution with patients with diarrhoea. Hyoscine should be used with caution in patients with ulcerative colitis as use may lead to ileus or megacolon.

Hyoscine may aggravate gastro-oespophageal reflux.

In case severe unexplained abdominal pain persists or worsens or occurs together with symptoms like fever, nausea, vomiting, changes in bowl movements, abdominal tenderness, decreased blood pressure, fainting or blood in stool, appropriate diagnostic measures are needed to investigate the aetiology of the symptoms.
Heat prostration can occur at high ambient temperatures, due to decreased sweating. Hyoscine should be administered with caution to patients with pyrexia.

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as hyoscine in patients with undiagnosed and therefore untreated angle-closure glaucoma. Urgent ophthalmological advice should be sought in case patients should develop a painful, red eye with loss of vision after the injection of hyoscine.

After parenteral administration of hyoscine, cases of anaphylaxis including episodes of shock have been observed. As with all drugs causing such reactions, patients receiving hyoscine by injection should be kept under observation.
Children: Use with caution in children as they may be more susceptible to adverse effects.

4.5 Interactions with other medicinal products and other forms of interaction

Anticholinergics/antimuscarinics: Many drugs have anticholinergic effects; concomitant use of two or more such drugs can increases side-effects such as dry mouth, urine retention and constipation; concomitant use can also lead to confusion in the elderly.

Anticholinergic (antimuscarinic) side-effects may be intensified by concomitant use of hyoscine with drugs such as tricyclic and tetracyclic antidepressants, monoamine oxidase inhibitors (MAOIs), antihistamines, quinidine, amantadine, antipsychotics (e.g. phenothiazines, butyrophenones, clozapine), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by hyoscine. .

Nitrates: Reduced effect of sub-lingual nitrates (failure to dissolve under the tongue due to dry mouth).

Beta-adrenergic agents: The tachycardic effects of beta-adrenergic agents may be enhanced by hyoscine.

Metoclopramide and Domperidone – Dopamine antagonist: Although hyoscine is not indicated for gastrointestinal treatment, concomitant treatment with dopamine antagonists such as metoclopramide or domperidone may result in diminution of the effects of both drugs on the gastrointestinal tract.

Dopaminergics: Hyoscine may reduce absorption of levopdopa

Alcohol: Patients should be advised to avoid alcohol prior to having any procedure which requires administration of hyoscine as an increased sedative effect has been reported when hyoscine is given with alcohol.

Parasympathomimetics: Hyoscine antagonises the effects of parasympathomimetics

4.6 Fertility, pregnancy and lactation

Pregnancy: There are limited data from the use of hyoscine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Hyoscine crosses the placenta. Use of hyoscine during pregnancy may cause respiratory depression in the neonate. As a precautionary measure hyoscine is not recommended during pregnancy.

Breast-feeding: There is insufficient information on the excretion of hyoscine and its metabolites in human milk. A risk to the breastfeeding child cannot be excluded. Use during breastfeeding is not recommended.

Fertility: No studies on the effects on human fertility have been conducted.

4.7 Effects on ability to drive and use machines

Hyoscine may cause drowsiness, dizziness or blurred vision. If affected, patients must not drive or operate machinery.

4.8 Undesirable effects

Many of the listed undesirable effects can be assigned to the anticholinergic properties of hyoscine.

Immune system disorders: anaphylactic shock including cases with fatal outcome, anaphylactic or anaphylactoid reactions, dyspnoea, skin reactions (e.g. urticaria, rash, erythema, pruritus) and other hypersensitivity

Psychiatric disorders: mental confusion or excitement, psychotic disorder, delirium, hallucinations

Nervous system disorders: drowsiness, dizziness, headache, loss of consciousness, neuroleptic malignant syndrome

Eye disorders: blurred vision, dilation of the pupils, with loss of accommodation, photophobia, angle-closure glaucoma

Cardiac disorders: transient bradycardia, tachycardia, palpitations, arrhythmias

Vascular disorders: blood pressure decreased, flushing

Gastrointestinal disorders: dry mouth, constipation, nausea, vomiting, difficulty in swallowing

Skin and subcutaneous tissue disorders: dyshidrosis, skin dryness

Renal and urinary disorders: difficulty with micturition

General disorders and administration site conditions: idiosyncratic reactions, injection site pain, particularly after intramuscular use, occurs, thirst

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 www.mhra.gov.uk/yellowcard.

4.9 Overdose

Symptoms:
Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdosage, anticholinergic symptoms such as urinary retention, dry mouth, reddening of the skin, tachycardia, inhibition of gastrointestinal motility and transient visual disturbances may occur.

Cheynes-Stokes respiration has been reported. Other symptoms may include dilated pupils, hyperthermia, hyperpyrexia, hypertension, nausea and vomiting. Toxic doses may also cause CNS stimulation marked by restlessness, confusion, excitement, ataxia, incoordination, paranoid and psychotic reactions, hallucinations, delirium, and occasionally seizures. In severe overdoage, central stimulation may give way to CNS depression, coma circulatory and respiratory failure and death.

Treatment:
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, however, such use is hazardous and is not generally recommended. Diazepam may be given to control excitement. For patients with glaucoma, pilocarpine should be given locally. Cardiovascular complications should be treated according to usual therapeutic principles. In cases of respiratory paralysis, intubation and artificial respiration should be undertaken. Catheterisation may be required for urinary retention.

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, secretory 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 (47%)
Sodium hydroxide
Water for injections

6.2. Incompatibilities

None stated

6.3. Shelf life

24 months

6.4. Special precautions for storage

Do not store above 25°C
Store in the original container.

6.5. Nature and contents of container

1ml neutral glass (Type I) ampoules in packs of 5 or 10.

6.6. Instruction for use and handling (, and disposal)

None stated

7. MARKETING AUTHORISATION HOLDER

Wockhardt UK Limited
Ash Road North
Wrexham
LL13 9UF
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 29831/0115

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/10/2024

10 DATE OF REVISION OF THE TEXT

29/10/2024