PROFESSIONAL INFORMATION

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml solution for injection

COMPOSITION:

Each 1 ml of injection contains 20 mg **Hyoscine Butylbromide**.

Excipients: hydrobromic acid and water for injection.

CATEGORY AND CLASS:

A: 11.2 Gastro- intestinal antispasmodics and cholinolytics (anticholinergics).

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Hyoscine butylbromide is a quaternary ammonium antimuscarinic agent. Hyoscine butylbromide does not readily pass the blood-brain barrier. It is a competitive antagonist of the actions of acetylcholine and other muscarinic agonists. The receptors affected, are those of peripheral structures that are either stimulated or inhibited by muscarine, i.e. exocrine glands, smooth and cardiac muscle. The peripheral effects are similar to those of atropine, but weaker and of shorter duration.

INDICATIONS:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

Is used in the treatment of conditions associated with gastrointestinal spasm.

CONTRAINDICATIONS:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml is contraindicated in:

- Patients who show hypersensitivity to hyoscine butylbromide or any other component of the product.
- Patients with tachycardia, hypotension, cardiac diseases or history of cardiac disease or hypertension.
- Patients who suffer from porphyria.
- Patients who suffer from myasthenia gravis; unless it is to reduce the adverse muscarinic effects of an anticholinesterase agent.
- Patients with prostatic enlargement, paralytic ileus or pyloric stenosis and fever.
- Patients who are pregnant or breastfeeding as the safety in pregnancy and lactation has not been established (see **HUMAN REPRODUCTION**).

WARNINGS and SPECIAL PRECAUTIONS

Warnings

- In patients who suffer from ulcerative colitis its use may lead to ileus or megacolon, and its effects on the lower oesophageal sphincter may exacerbate reflux.
- It should be given with caution to patients with diarrhoea, closed angle glaucoma, or narrow angle between the iris and cornea, as the hyoscine butylbromide component increases intra-ocular pressure.
- It should be given with caution to elderly patients and patients with impaired metabolic, liver or kidney function as adverse CNS (central nervous system) effects are more likely to occur in these patients (see **INTERACTIONS**).
- After parenteral administration of **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml**, cases of anaphylaxis including episodes of shock may be observed. As with all medicines causing such reactions, patients receiving this injection should be kept under observation.

Special Precautions:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

- Can cause tachycardia, hypotension and anaphylaxis, therefore use with caution in patients with cardiac conditions such as cardiac failure, coronary heart disease, cardiac arrhythmia or hypertension, and in cardiac surgery.

  Screening and monitoring of these patients is advised. Emergency equipment and personnel trained in its use must be readily available.
- It should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, cardiac insufficiency or failure, and in cardiac surgery, where it may further accelerate the heart-rate.
- Care is required in patients with acute myocardial infarction as ischaemia and infarction may be worsened.
- It should be given with care to patients with hypertension.
- In elderly patients and in patients with impaired metabolic, liver or kidney function, adverse central nervous system effects such as disorientation, delirium or somnolence is more likely to occur (see **INTERACTIONS**).
- It should be given with caution to patients with diarrhoea.
- It should be used with caution in children and in geriatric patients, who may be more susceptible to its adverse effects.

Effects on the ability to drive and use machines:

Patients who experience drowsiness should not drive or operate machinery.

Alcohol should be avoided.

INTERACTIONS:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml may interact with other medicines:

The tachycardic effects of beta-adrenergic agents may be enhanced by **Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml.**

It should be used with care in patients receiving other central depressants concomitantly, as central nervous system depression may be enhanced (see **WARNINGS and SPECIAL PRECAUTIONS**).

The effects of antimuscarinic agents may be enhanced by medicines with antimuscarinic properties, such as amantadine, some antihistamines, butyrophenones and phenothiazines, and tricyclic antidepressants.

HUMAN REPRODUCTION:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

- It should not be given to pregnant and lactating mothers as safety has not yet been established (see **CONTRAINDICATIONS**).
- It has been stated to cross the placenta.

DOSAGE AND DIRECTIONS FOR USE:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml:

For adults and children over 12 years of age:

The usual dose is:

- 20 mg given intramuscularly or intravenously, 2 to 3 times daily.
- It should be repeated after 30 minutes, if necessary.
- The maximum daily dose of 100 mg should not be exceeded.
- Patients should be observed for side-effects following parenteral administration.

Children up to 6 years:

10 mg given intramuscularly or intravenously.

Infants and children up to 3 years:

5 mg given intramuscularly or intravenously.

SIDE EFFECTS:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml may have side effects

Immune system disorders:

Frequency unknown: anaphylactic shock including cases with fatal outcome, anaphylactic reactions, dyspnoea, skin reactions (e.g. urticaria, rash, erythema, pruritus) and other hypersensitivity.

Nervous system disorders:

Frequency unknown: Giddiness and staggering may occur.

Eye disorders:

Frequency unknown: Dilatation of the pupils with loss of accommodation and photophobia and increased intra-ocular pressure.

Cardio-Vascular disorders:

Frequent: tachycardia

Frequency unknown: Bradycardia followed by tachycardia, with palpitations and arrhythmias.

Gastro-intestinal disorders:

Frequency unknown: Dryness of the mouth, with difficulty in swallowing, thirst, reduction in the tone and motility of the gastro-intestinal tract, leading to constipation, vomiting and retrosternal pain may occur due to increased gastric reflux.

Skin and subcutaneous disorders:

Frequency unknown: Flushing, dryness of the skin, hypersensitivity reactions, including skin reactions.

Renal and urinary disorders:

Frequency unknown: Urinary urgency with the inability to do so.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Pharma-Q Hyoscine Butylbromide Injection 20 mg/1 ml overdose:

- Toxic doses cause tachycardia, rapid respiration, hyperpyrexia, restlessness, confusion, excitement, impotence and hallucinations passing into delirium.
- A rash may appear on face and upper trunk.
- In severe intoxication, depression of the central nervous system may occur with circulatory failure and respiratory failure.
- Quaternary ammonium anticholinergic agents usually have some ganglion blocking action, so that high doses may cause postural hypertension and impotence.
- In toxic doses, nondepolarising neuromuscular block may be produced.
- Treatment of overdosage: Physostigmine 1 to 2 mg may be injected repeatedly if necessary.
- Supportive and symptomatic therapy should be given as required.

IDENTIFICATION:

Clear, colourless solution in amber ampoules.

PRESENTATION:

Amber ampoules containing 20 mg/1 ml in containers of 10 or 100.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

32/11.2/0242.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE

OF REGISTRATION:

PHARMA-Q HOLDINGS (PTY) LTD

50 COMMANDO ROAD

INDUSTRIA WEST, 2093

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