1. Name of the proprietary product

Hyoscine Butylbromide Injection Vega 10mg/ml Injection

2. Qualitative and Quantitative composition:

Hyoscine Butylbromide Injection 10mg/ml

3. Pharmaceutical Form

Solution for injection

A clear & colourless solution

4. Clinical Particulars

4.1 Therapeutic Indications

Hyoscine Butylbromide Injection is indicated for the relief of acute genitourinary or gastrointestinal spasm.

4.2 Posology and method of administration

One ampoule (10 mg) intramuscularly or intravenously, repeated after half an hour if necessary. Intravenous injection should be performed 'slowly'. When used in endoscopy this dose may need to be repeated more frequently.

Maximum daily dose of 100mg.

Special populations

Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

One ampoule (10 mg) intramuscularly or intravenously, repeated after half an hour if necessary. Intravenous injection should be performed 'slowly' When used in endoscopy this dose may need to be repeated more frequently.

Maximum daily dose of 100mg.

Special populations

Elderly: No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this age group have been reported.

4.3 Contraindications

Hyoscine Butylbromide Injection are contraindicated in patients with:

- hypersensitivity to the active substance or to any of the excipients

- narrow angle glaucoma

- hypertrophy of the prostate with urinary retention
- mechanical stenosis in the gastrointestinal tract

- paralytical or obstructive ileus

- megacolon

- tachycardia

- myasthenia gravis

Hyoscine Butylbromide Injection 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

In case severe, unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, nausea, vomiting, changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting, or blood in stool, appropriate diagnostic measures are needed to investigate the aetiology of the symptoms.

Hyoscine Butylbromide Injection 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. Monitoring of these patients is advised. Emergency equipment and personnel trained in its use must be readily available.

Because of the possibility that anticholinergics may reduce sweating, Hyoscine Butylbromide Injection 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 Butylbromide Injection in patients with undiagnosed and therefore untreated narrow angle glaucoma. Therefore, patients should seek urgent ophthalmological advice in case they should develop a painful, red eye with loss of vision after the injection of Hyoscine Butylbromide Injection.

After parenteral administration of Hyoscine Butylbromide Injection cases of anaphylaxis including episodes of shock have been observed. As with all drugs causing such reactions, patients receiving Hyoscine Butylbromide Injection by injection should be kept under observation.

4.5 Interaction with other medicinal products and other forms of interaction: The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, quinidine, amantadine, antipsychotics (e.g. phenothiazines, butyrophenones), disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Hyoscine Butylbromide Injection.

The tachycardic effects of beta-adrenergic agents may be enhanced by Hyoscine Butylbromide Injection.

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.

4.6 Pregnancy and Lactation Pregnancy

There are limited data from the use of hyoscine butylbromide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. As a precautionary measure is Hyoscine Butylbromide Injection not recommended during pregnancy.

Lactation

There is insufficient information on the excretion of hyoscine butylbromide and its metabolites in human milk. A risk to the breastfeeding child cannot be excluded. Use of Hyoscine Butylbromide Injection during breastfeeding is not recommended.

4.7 Effects on the ability to drive and use machines

However, patients should be advised that they may experience undesirable effects such as accommodation disorder or dizziness during treatment with Hyoscine Butylbromide Injection. Therefore, caution should be recommended when driving a car or operating machinery. If patients experience accommodation disorder or dizziness, they should avoid potentially hazardous tasks such as driving or operating machinery.

4.8 Undesirable effects:

Many of the listed undesirable effects can be assigned to the anticholinergic properties of Hyoscine Butylbromide Injection.

Adverse events have been ranked under headings of frequency using the following convention:

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1000, <1/100); rare (≥ 1/10000, <1/1000); very rare (<1/10000); not known – cannot be estimated from the available data.

Immune system disorders

Uncommon: skin reactions (e.g. urticaria, pruritus)

Not known*: anaphylactic shock , anaphylactic reactions, dyspnoea, rash, erythema, other hypersensitivity

Cardiac disorders

Uncommon: tachycardia

Gastrointestinal disorders:

Uncommon: dry mouth

Skin and subcutaneous tissue disorders

Uncommon: dyshidrosis

Renal and urinary disorders

Rare: urinary retention

* This adverse reaction has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than uncommon (3/1,368), but might be lower.

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, and Cheynes-Stokes respiration has been reported.

Therapy

Symptoms of Hyoscine Butylbromide Injection overdosage respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration should be considered.

Catheterisation may be required for urinary retention.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antispasmodics

ATC code: A03BB01

Hyoscine belongs to the group of medications called antispasmodics. Hyoscine is used to relieve smooth muscle spasms (cramps) in the stomach and intestines and in the bladder and urethra. Hyoscine reduces spasms by relaxing smooth muscles within the stomach, intestines, bladder and urethra.

5.2 Pharmacokinetic properties Absorption and distribution

After intravenous administration hyoscine butylbromide is rapidly distributed ($t_{½\alpha}$ = 4 min, $t_{½\beta}$ = 29 min) into the tissues. The volume of distribution (Vss) is 128 L

(corresponding to approx. 1.7 L/kg). Because of its high affinity for muscarinic receptors and nicotinic receptors, hyoscine butylbromide is mainly distributed on muscle cells of the abdominal and pelvic area as well as in the intramural ganglia of the abdominal organs. Plasma protein binding (albumin) of hyoscine butylbromide is approximately 4.4%. Animal studies demonstrate that hyoscine butylbromide does not pass the blood-brain barrier, but no clinical data to this effect is available. Hyoscine butylbromide (1 mM) has been observed to interact with the choline transport (1.4 nM) in epithelial cells of human placenta *in vitro*.

Metabolism and elimination

The main metabolic pathway is the hydrolytic cleavage of the ester bond. The half-life of the terminal elimination phase ($t_{½γ}$) is approximately 5 hours. The total clearance is 1.2 L/min. Clinical studies with radiolabeled hyoscine butylbromide show that after intravenous injection 42 to 61% of the radioactive dose is excreted renally and 28.3 to 37% faecally.

The portion of unchanged active ingredient excreted in the urine is approximately 50%. The metabolites excreted via the renal route bind poorly to the muscarinic receptors and are therefore not considered to contribute to the effect of the hyoscine butylbromide.

Paediatric population

No particular pharmacokinetic studies concerning hyoscine butylbromide have been performed in children.

5.3 Pre-clinicalSafety

Not Applicable

6. Pharmaceutical Particulars:

List of Excipients:

Methyl paraben	BP
Glacial Acetic acid	BP
Sodium Acetate Trihydrate	BP
Sodium Chloride	BP
Mannitol	BP
Water for Injections	BP

6.2 Incompatibilities:

Not applicable

6.3 Shelf Life: 36 months

6.4 Special Precautions for storage:
Store at a temperatur below 30°C, protect from light.

6.5 Nature and contents of container:
1ml amber ampoule packed in PVC tray (10 x 1 ml) along with primary carton and pack insert.

6.6 Special precautions for disposal and other handling:
No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

VEGAGEN UK LIMITED.
THE LITTON SUITE SHEEPBRIDGE
BUSINESS CENTER CHESTERFIELD S41.9ED,
UK.

8. Marketing Authorization Number

FDA/SD.255-030349

9. Date of first Authorization /renewal of the authorization

03/03/2025

10. Date of revision of text

10/2025