SUMMARY OF PRODUCT CHARACTERISTIC

1. Name of the medicinal product

HYOCIN - Hyoscine Butylbromide Injection BP

2. Qualitative and quantitative composition

Each ml contains:

Hyoscine butylbromide BP 20.40mg.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid Injection.

A clear colorless solution free from particulate matter and fibers

4. Clinical particulars

4.1 Therapeutic indications

Hyoscine butylbromide is indicated in acute spasm, as in renal or biliary colic, in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem (e.g. gastroduodenal endoscopy).

4.2 Posology and method of administration

Adults

One ampoule (20 mg) intravenously or intramuscularly, repeated after half an hour if necessary. Intravenous injection should be performed 'slowly' (in rare cases a marked drop in blood pressure and even shock may be produced by hyoscine injection).

When used in endoscopy this dose may need to be repeated more frequently.

Maximum daily dose is 100 mg (5 ampoules).

Special populations

Elderly: No specific information on the use of this medicine 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.

Paediatric population

Not recommended.

Hyoscine butylbromide injection should not be used on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

Method of administration

For intravenous and intramuscular injection.

Hyoscine butylbromide 20 mg/ml solution for injection may be used diluted with glucose or with sodium chloride 0.9% solution for injection (see section 6.6).

4.3 Contraindications

Hyoscine butylbromide is contraindicated in patients with:

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- narrow angle glaucoma
- prostate hypertrophy with urinary retention
- mechanical stenosis in the gastrointestinal tract
- paralytic or obstructive ileus
- megacolon
- tachycardia
- myasthenia gravis

Hyoscine butylbromide 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 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 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 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.

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

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. is essentially "sodium-free".

4.5 Interaction with other medicinal products and other forms of interaction

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, antipsychotics (e.g. phenothiazines,butyrophenones), quinidine, disopyramide, amantadine, and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by hyoscine butylbromide.

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

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

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data on the use of hyoscine butylbromide in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). As a precautionary measure, hyoscine butylbromide is not recommended during pregnancy.

Breast-feeding

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 during breast-feeding 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

No studies on the effects on the ability to drive and use machines have been performed. However, patients should be advised that they may experience undesirable effects such as accommodation disorders or dizziness during treatment with hyoscine butylbromide. Therefore, caution should be observed when driving a car or operating machinery. If patients experience accommodation disorders 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.

Undesirable effects are listed by system organ classes by using the following frequency convention:

Very common	≥1/10
Common	≥1/100, <1/10
Uncommon	≥1/1,000, <1/100
Rare	≥1/10,000, <1/1,000

Very rare	<1/10,000
Not known	cannot be estimated from the available data

Immune system disorders

Not known*: anaphylactic shock including cases with fatal outcome, anaphylactic reactions, dyspnoea, skin reactions (e.g. urticaria, rash, erythema, pruritus) and other hypersensitivity reactions.

Eye disorders

Common: accommodation disorders.

Not known*: mydriasis, increased intraocular pressure.

Cardiac disorders

Common: tachycardia.

Vascular disorders

Common: dizziness.

Not known*: blood pressure decreased, flushing.

Gastrointestinal disorders

Common: dry mouth, constipation.

Skin and subcutaneous tissue disorders

Not known*: dyshidrosis.

Renal and urinary disorders

Not known*: urinary retention.

Injection site pain, particularly after intramuscular use, occurs.

Hyoscine butylbromide due to its chemical structure as a quaternary ammonium derivate, is not expected to enter the central nervous system. Hyoscine butylbromide does not readily pass the blood-brain barrier. However, it cannot totally be ruled out that under certain circumstances psychiatric disorders (e.g. confusion) may also occur after administration of this medicine.

4.9 Overdose

Symptoms

Serious signs of poisoning following acute overdosage have not been observed in man. In the case of overdose, 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.

Treatment

Symptoms of hyoscine butylbromide overdose 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 and artificial respiration should be considered. Catheterisation may be required for urinary retention.

In addition, appropriate supportive measures should be used as required.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Belladonna alkaloids, semisynthetic, quaternary ammonium compounds, ATC code: A03BB01.

Hyoscine butylbromide is an antispasmodic agent which relaxes smooth muscle of the organs of the abdominal and pelvic cavities. It is believed to act predominantly on the intramural parasympathetic ganglia of these organs.

Hyoscine butylbromide, due to its chemical structure as a quaternary ammonium derivate, is not expected to enter the central nervous system. Hyoscine butylbromide does not readily pass the blood-brain barrier. However, it cannot totally be ruled out that under certain circumstances psychiatric disorders (e.g. confusion) may also occur after administration of hyoscine butylbromide.

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 is 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 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.

Metabolism and elimination

The main metabolic pathway is the hydrolytic cleavage of the ester bond. The terminal half-life is approximately 5 hours. The total clearance is 1.2 l/min. After intravenous injection, 42 to 61% of the dose is excreted in urine and 28.3 to 37% in faeces. Approximately 50% of the dose is excreted in urine unchanged. 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.

5.3 Preclinical safety data

In limited reproductive toxicity studies hyoscine butylbromide showed no evidence of teratogenicity in rats at 200 mg/kg in the diet or in rabbits at 200 mg/kg by oral gavage or 50 mg/kg by subcutaneous injection. Fertility in the rat was not impaired at doses of up to 200 mg/kg in the diet.

6. Pharmaceutical particulars

6.1 List of excipients

Glacial acetic acid

Methyl Hydroxy benzoate

Sodium Acetate

Water for injections

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30 °C. Protect from light.
Do not freeze.

6.5 Nature and contents of container

2x5x1 ml amber ampoules in Blister

6.6 Special precautions for disposal and other handling

For single use only. Once opened, any unused portion should be discarded.

The medicinal product is to be visually inspected prior to use. Only clear solutions free from particles should be used.

Hyoscine butylbromide 20 mg/ml solution for injection may be diluted with glucose or with sodium chloride 0.9% solution for injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

SAKAR Healthcare Limited

Block No. 10-13, Sarkhej-Bavla Highway,

Changodar, Ahmedabad – 382213, Gujarat, India

8. Marketing authorisation number(s)

06902/08234/REN/2021

9. Date of first authorisation/renewal of the authorisation

01/11/2021

10. Date of revision of the text

July 2023