Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Dysmin Injection (Hyoscine Butylbromide Injection 20mg/ml)

2. Qualitative and quantitative composition

Each ml contains:
Hyoscine Butylbromide BP 20mg
Water

3. Pharmaceutical form

Injection

Clear, colourless or almost colourless solution free from visible particles.
pH of solution 3.7–5.5.

4. Clinical particulars

4.1 Therapeutic indications

Acute spasm of the gastrointestinal tract, biliary tract, pancreas and urogenital tract. As antispasmodic agent in radiology in different diagnostic procedures where spasm may be a problem (e.g. gastroduodenal endoscopy).

4.2 Posology and method of administration

Posology Adults and children over 12 years of age: The dose is 20□40 mg (1□2 ampoules) administered intravenously slowly, intramuscularly or subcutaneously. Maximum daily dose is 100 mg (5 ampoules).

Paediatric population

In severe cases, in infants and children the dose 0.3□0.6 mg/kg body weight may be administered intravenously slowly, intramuscularly or subcutaneously several times daily. The maximum daily dose of 1.5 mg/kg body weight should not be exceeded.

Method of administration

For intravenous, intramuscular or subcutaneous injection. Scopolamine butylbromide Kalceks may be used diluted (see section 6.6). Hyoscine butylbromide injection should not be used on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

4.3 Contraindications

– 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.
– 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. Patients receiving hyoscine butylbromide should be kept under observation. Caution should be exercised in patients with cardiovascular disease receiving parenteral treatment with hyoscine butylbromide. Monitoring of these patients is recommended.

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, quinidine, disopyramide, amantadine, and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified 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. The tachycardic effects of beta-adrenergic agents may be enhanced by hyoscine butylbromide.

4.6 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).

Breast-feeding
There is insufficient information on the excretion of hyoscine butylbromide and its metabolites in human milk. Use of hyoscine butylbromide during breast-feeding is not recommended.

Fertility
No studies on the effects on human fertility have been performed.

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. 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 such undesirable effects, 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. Anticholinergic side effects of hyoscine butylbromide are usually mild and transient. Undesirable effects are listed according to the MedDRA system organ classes by using the following frequency convention:

Very common ≥1/10

Common ≥1/100

Uncommon ≥1/1,000

Rare ≥1/10,000

Immune system disorders

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

Skin and subcutaneous tissue disorders Not known: dyshidrosis*.

Renal and urinary disorders

Not known: urinary retention*

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 exerts a spasmolytic effect on the smooth muscle of the gastrointestinal tract, biliary tract and urogenital tract. Hyoscine-N-butyl bromide is a quaternary ammonium compound and does not cross the blood-brain barrier to the central nervous system. Therefore, no anticholinergic side effects are seen from the CNS. The peripheral anticholinergic effect of hyoscine-N-butyl bromide is due in part to blockade of para-sympathetic ganglia in the intestinal wall and partly to an anti-muscarine effect.

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 (approximately 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

Methyl Paraben
Water for injection

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

Unopened ampoule:36months.

Shelf life after first opening: The medicinal product should be used immediately after opening the ampoule.

Shelf life after dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C and 2-8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special Precautions for storage

Store in dry place below 30^0C. Protect from light.

6.5 Nature and Content of container

5 x 1ml ampoules packed in a transparent tray, such a tray is packed in a carton with insert**.**

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 Authorization Holder

PROMED PHARMACEUTICAL LTD.
Atraco House, Wood Avenue,

Kilimani-Nairobi, Kenya

8. Marketing Authorization Number

CTD9512

9. Date of first authorization/renewal of the authorization

14th March 2023

10. Date of revision of the text

11th May 2025