SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Scopinal 20mg/mL Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each (1mL) ampoule contains:

Item No.	Material Name	Scale (mg/1mL ampoule)
	Active Ingredient:	
1.	Hyoscine-N-Butylbromide	20.00
	Inactive Ingredients:	
2.	Hydrobromic acid	q.s. to pH adjustment
3.	Water for injection	q.s. to 1mL
4.	Nitrogen gas *	q.s.

* Nitrogen gas does not appear in the final product.

3. PHARMACEUTICAL FORM

Solution for Injection

Description: Clear, colourless solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Scopinal 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. gastro-duodenal endoscopy.

4.2 Posology and method of administration

Adults:
One ampoule (20 mg) intramuscularly or intravenously or subcutaneously, 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 butylbromide). 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.

Paediatric population

Not recommended for children.
Scopinal should not be taken on a continuous daily basis or for extended periods without investigating the cause of abdominal pain.

Diluent:

Scopinal may be diluted with dextrose or with sodium chloride 0.9% injection solutions.

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

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 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 (see section 5.3). As a precautionary measure hyoscine butylbromide is 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 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

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 disorder or dizziness during treatment with hyoscine butylbromide. 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.
Adverse events have been ranked under headings of frequency using the following 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.

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, the active ingredient of **Scopinal**, 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 butalybromide.

*This adverse reaction has been observed in post-marketing experience. With 95% certainty, the frequency category is not greater than common, but might be lower. A precise frequency estimation is not possible as the adverse drug reaction did not occur in a clinical trial database of 185 patients.

Healthcare professionals are asked to report any suspected adverse reactions via:
Pharmacovigilance and Medical Device Section
Drug Department - U.A.E M.O.H
Hotline: 80011111
Email: pv@moh.gov.ae
P.O. Box: 1853 Dubai U.A.E.

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 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 and artificial respiration. Catheterisation may be required for urinary retention.
In addition, appropriate supportive measures should be used as required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Scopinal 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.

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 ($t_{½\gamma}$) 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 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

Inactive Ingredients:

1. Hydrobromic acid
2. Water for injection
3. Nitrogen gas *

* Nitrogen gas does not appear in the final product.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months from the date of manufacturing

6.4 Special precautions for storage

Store below 30°C. Protect from light and heat

6.5 Nature and contents of container

- 1mL ampoule with a printed label, 5 ampoules in an ampule tray, packed in a printed carton along with a leaflet.
- 50 x 1mL ampoule with a printed label, 5 ampoules in an ampoule tray, packed in a printed carton along with a leaflet.

6.6 Special precautions for disposal and other handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Gulf Pharmaceutical Industries - Julphar
Digdaga, Airport Street
Ras Al Khaimah - United Arab Emirates
P.O. Box 997
Tel. No.: (9717) 2 461 461
Fax No.: (9717) 2 462 462

8. MARKETING AUTHORISATION NUMBER(S)

09134/08400/REN/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Dec 4, 2023

10. DATE OF REVISION OF THE TEXT

19. March. 2019