YSP Hyoscine
Injection 20MG/ML

Ingredient(s):
Each ml contains:
Hyoscine N-Butylbromide 20mg

List of excipients:
Sodium Chloride,Hydrochloric Acid & Water for Injection

Pharmacology (Summary of Pharmacodynamic and Pharmacokinetic):
Pharmacodynamics:
YSP Hyoscine Injection 20mg/ml 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.

Pharmacokinetics:
Absorption and distribution
After intravenous administration hyoscine butylbromide is rapidly distributed ($t_{1/2\alpha}$ = 4 min, $t_{1/2\beta}$ = 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%. Hyoscine butylbromide (1mM) has been observed to interact with choline transport (1.4 nM) in epithelial cells of human placenta *in vitro*.

Metabolism and elimination
The main metabolic pathway is the hydrolic cleavage of the ester bond. The half-life of the terminal elimination phase ($t_{1/2\gamma}$) is approximately 5 hours. The total clearance is 1.2 L/min. 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 hyoscine butylbromide have been performed in children.

Indication(s):
YSP Hyoscine Injection 20mg/ml is indicated in acute spasm, as in renal or biliary colic, in radiology for differential diagnosis of obstruction. It also indicated to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem.

Dosage and Administration(s):
YSP Hyoscine Injection 20mg/ml may be administered by Intramuscular or intravenous injection.

Adults
One ampoule (20mg) should be given Im or IV, 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). When used in endoscopy this dose may need to be repeated more frequently. Maximum daily dose of 100mg.
Not recommended for children under 12 years old.

Mode of Administration:
Intramuscular or intravenous

Contraindications:
YSP Hyoscine Injection 20mg/ml 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

YSP Hyoscine Injection 20mg/ml should not be given by intramuscular injection to patients being treated with anticoagulant drugs since intramuscular haematoma may occur.

Precaution(s) / Warning(s):
Pregnancy/reproduction:
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 of blood pressure, fainting, or blood in stool, appropriate diagnostic measures are needed to investigate the etiology of the symptoms.

YSP Hyoscine Injection 20mg/ml can cause tachycardia, hypotension and anaphylaxis, therefore use with caution in patients with cardiac conditions such as cardiac failure, coronary heart disease or cardiac arrhythmia and patients with cardiovascular disease (e.g. acute myocardial infarction, hypertension and conditions associated with tachycardia 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, YSP Hyoscine Injection 20mg/ml should be administered with caution to patients with pyrexia.

Elevation of intraocular pressure may be produced by the administration of anticholinergic agents such as YSP Hyoscine Injection 20mg/ml 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 YSP Hyoscine Injection 20mg/ml.

After parenteral administration of YSP Hyoscine Injection 20mg/ml, case of anaphylaxis including episodes of shock have been observed. As with all drugs causing such reactions, patients receiving YSP Hyoscine Injection 20mg/ml by injection should be kept under observation.

Interaction with Other Medicaments:
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 YSP Hyoscine Injection 20mg/ml. The tachycardiac effects of beta-adrenergic agents may be enhanced by YSP Hyoscine Injection 20mg/ml. Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.

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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 YSP Hyoscine Injection 20mg/ml 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 YSP Hyoscine Injection 20mg/ml is not recommended.

Fertility

No studies on the effects on human fertility have been conducted.

Undesirable effects:

Many of the listed undesirable effects can be assigned to the anticholinergic properties of YSP Hyoscine Injection 20mg/ml.

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

Very common	(≥ 1/10)
Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 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, dyspnea, 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 YSP Hyoscine Injection 20mg/ml, 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 circumstance psychiatric disorders (e.g. confusion) may also occur after administration of YSP Hyoscine Injection 20mg/ml.

*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.

Symptoms and Treatment for Overdosage, and Antidote(s):

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 YSP Hyoscine Injection 20mg/ml 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.

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

Effects on Ability to Drive and use Machine:

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 YSP Hyoscine Injection 20mg/ml. 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.

Shelf-Life:

3 years from the date of manufacture

Storage Condition(s):

Store at temperature below 30ºC. Protect from light and moisture.

Product Description:

A clear and colorless solution.

Dosage Forms and Packaging available:

1ml x 10, 1ml x 50 and 1ml x 100 Ampoules

Not all presentations may be available locally.

Y. S. P.®

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
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Date of revision: 01 Jun 2023

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