

Summary Product Characteristics (SPC)

1 Name of the Medical Product:

1.1 Product Name: SPASMODEX-P

1.2 Strength: Paracetamol 500 mg & Hyoscine Butylbromide 10 mg

1.3 Pharmaceutical Dosage Form : Tablet , Solid Dosage form

2.0 Quality and Quantitative Composition :

Each film coated tablet contains:

Paracetamol BP 500 mg

Hyoscine butylbromide BP 10 mg

Titanium Dioxide BP

For full list of excipients, see section 6.1 of SmPC

3.0 Pharmaceutical Dosage Form :

Tablet, Solid Dosage form

4.0 Clinical Particulars :

4.1 Therapeutic Indications :

Hyoscine butylbromide + Paracetamol is an antispasmodic-analgesic combination used for the relief from the pain of stronger abdominal cramps including menstrual cramps and urinary tract spasm.

4.2 Posology and method of administration

Hyoscine butylbromide + Paracetamol should not be taken over prolonged period of time (for more than 3 days) without a prescription from the physician.

The following doses are recommended: Adults: 1-2 tablets, 3 times daily.

The total daily dose should not exceed 6 tablets.

Pediatric population: Not suitable for children under 10 years of age.

Method of administration

For oral administration only.

Should be swallowed whole with adequate water.

4.3 Contraindications

Hypersensitivity to any of Excipient used.

Myasthenia gravis, mechanical stenosis in the GIT, paralytic or obstructive ileus, megacolon, severe hepatocellular insufficiency (Child-Pugh C), rare hereditary conditions.

4.4 Special Warnings and precaution for use

Seek medical advice in case of persisting severe, unexplained abdominal pain w/ symptoms eg, fever, nausea, vomiting, changes in bowel movement, abdominal tenderness, decreased BP, fainting or blood in stool. G6PD deficiency, hepatic or renal dysfunction, Gilbert's syndrome, hepatocellular insufficiency (Child-Pugh A/B). Monitor blood count, renal & liver function after prolonged use. Discontinue use at 1st signs of hypersensitivity reaction. Avoid abrupt discontinuation after prolonged use at high doses. Should not be taken >3 days. Patients prone to narrow-angle glaucoma, susceptible to intestinal or urinary outlet obstructions & inclined to tachyarrhythmia. Patients w/ Na restricted diet. Not recommended during pregnancy. Lactation. Childn <10 yr. Paracetamol: Other drugs containing paracetamol. May induce headaches w/ extensive use of high doses of analgesics.

In case a 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, medical advice should immediately be sought. To prevent overdosing, it should be ensured that any other drugs taken concurrently do not contain paracetamol, one of the active components of Hyoscine- butylbromide + Paracetamol. Liver damage may result if the recommended dosage for paracetamol is exceeded.

Hyoscine butylbromide + Paracetamol should be used with caution in: glucose-6-phosphate-dehydrogenase deficiency, hepatic dysfunction (e.g. due to chronic alcohol abuse, hepatitis), impaired renal function, Gilbert's syndrome, and hepatocellular insufficiency (Child-Pugh A/B).

In such cases Hyoscine butylbromide + Paracetamol should only be used under medical supervision and, if necessary, the dose reduced or the intervals between the individual administrations prolonged. The blood count and renal and liver function should be monitored after prolonged use.

Extensive use of analgesics, especially at high doses, may induce headaches that must not be treated with increased doses of the drug.

Severe acute hypersensitivity reactions (e.g. anaphylactic shock) are very infrequently observed. Treatment must be discontinued at the first signs of a hypersensitivity reaction following the administration of Hyoscine butylbromide + Paracetamol .

Abrupt discontinuation of analgesic after prolonged use at high doses may induce withdrawal symptoms (e.g. headache, tiredness, nervousness), that typically resolve within few days. Reintake of analgesics should depend upon physician's advice, and withdrawal symptoms abated.

Hyoscine butylbromide + Paracetamol should not be taken for more than 3 days unless directed by a physician. The patient should be instructed to seek medical advice, if pain persists or gets worse, if new symptoms occur, or if redness or swelling is present because these could be signs of a serious condition.

Because of the potential risk of anticholinergic complications, caution should be used in patients prone to narrow angle glaucoma as well as in patients susceptible to intestinal or urinary outlet obstructions and in those inclined to tachyarrhythmia.

4.5 Interaction with other medicinal products and other forms of interaction

Hyoscine butylbromide + Paracetamol can be taken together with other drugs but not with the following:

certain hypnotics and anti-epileptics (e.g. glutethimide, phenobarbital, phenytoin, carbamazepine) as well as rifampicin. The same applies to potentially hepatotoxic substances and alcohol abuse.

Long-term use of paracetamol in patients being treated with oral anti-coagulants is only advisable under medical supervision.

Concomitant use of paracetamol and zidovudine (AZT or retrovir) enhances the tendency towards reducing leukocytes (neutropenia). Therefore, Hyoscine butylbromide + Paracetamol should only be taken together with zidovudine following medical advice.

The paracetamol dose should be reduced during concurrent administration with probenecid.

Cholestyramine reduces the absorption of paracetamol.

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

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 + Paracetamol

4.6 Fertility, pregnancy and lactation

Pregnancy

Hyoscine butylbromide + Paracetamol Tablet may be unsafe to use during pregnancy.

Lactation

Hyoscine butylbromide + Paracetamol is safe to use during lactation.

Fertility

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

4.7 Effects on ability to drive and use machine :

No studies on the effects on the ability to drive and use machines have been performed. Because of possible visual accommodation disturbances patients should not drive or operate machinery if affected.

4.8 Undesirable Effects

Hyoscine butylbromide + Paracetamol tablets may cause:

Blood and lymphatic system disorders:

Pancytopenia, agranulocytosis, thrombocytopenia, leukopenia.

Immune system disorders, skin and subcutaneous tissue disorders:

Skin reactions, sweating abnormal, pruritus, urticaria, nausea, erythema, blood pressure decreased including shock, anaphylactic shock, anaphylactic reactions, drug eruption, dyspnoea, hypersensitivity, angioedema, rash, exanthema.

Very rare cases of serious skin reactions (such as Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) have been reported for paracetamol.

Cardiac disorders: Tachycardia.

Respiratory, thoracic and mediastinal disorders: Bronchospasm (especially in patients with a history of bronchial asthma or allergy).

Gastrointestinal disorders: Dry mouth.

Hepatobiliary disorders: Transaminases increased.

Renal and urinary disorders: Urinary retention.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS)

<https://pv.pharmacyboardkenya.org>

4.9 Overdose

Symptoms:

Signs of overdose of Hyoscine butylbromide may include pallor, nausea, vomiting, anorexia and abdominal pain. Patients may then experience a temporary subjective improvement but mild abdominal pain possibly indicative of liver damage may persist. A single dose of paracetamol of approximately 6 g or more in adults or 140 mg/kg in children may cause hepatocellular necrosis. This may lead to complete irreversible necrosis and subsequently to hepatocellular insufficiency, metabolic acidosis and encephalopathy, which may in turn progress to coma and death.

Concurrent rises in liver transaminases (AST, ALT), lactate dehydrogenase and bilirubin and an increase in prothrombin time, occurring 12 - 48 hours after ingestion, have been observed. Clinical symptoms of liver damage are normally apparent after 2 days and

reach a maximum after 4 - 6 days.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Other non-hepatic symptoms such as myocardial abnormalities and pancreatitis have also been reported to occur after paracetamol overdosage.

Treatment:

If required, parasympathomimetic drugs should be administered. Ophthalmological advice should be sought urgently in cases of glaucoma. 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.

Where paracetamol intoxication is suspected, intravenous administration of SH group donors such as N-acetylcysteine within the first 10 hours after ingestion is indicated. Although N-acetylcysteine is most effective if initiated within this period, it can still offer some degree of protection if given as late

as 48 hours after ingestion; in this case, it is taken for longer. The plasma concentration of paracetamol can be decreased by dialysis. Determinations of the plasma concentration of paracetamol are recommended.

Further measures will depend on the severity, nature and course of clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.

5.0 Pharmacological Properties

Pharmacotherapeutic group : Antispasmodic-analgesic

Paracetamol : N02BE01 , Hyoscine Butylbromide : A03BB01

5.1 Pharmacodynamic Properties

Mechanism of action

Hyoscine butylbromide and Paracetamol/Acetaminophen, which relieves abdominal pain and cramps. Hyoscine butylbromide is an anti-cholinergic which works by relaxing the muscles in your stomach and gut (intestine). It stops sudden muscle contractions (spasms), thereby relieving cramps, pain, bloating, and discomfort. Paracetamol/Acetaminophen is an analgesic (pain reliever) which works by blocking the release of certain chemical messengers that cause pain.

5.2 Pharmacokinetic Properties

Hyoscine Butylbromide

Absorption

As a quaternary ammonium compound, hyoscine butylbromide is highly polar and hence only partially absorbed following oral (8%) or rectal (3%) administration. After oral administration of single doses of hyoscine butylbromide in the range of 20 to 400 mg, mean peak plasma concentrations between 0.11 ng/mL and 2.04 ng/mL were found at approximately 2 hours. In the same dose range, the observed mean AUC_{0-tz} values varied from 0.37 to 10.7 ng h/mL. The median absolute bioavailabilities of different dosage forms, i.e. coated tablets, suppositories and oral solution, containing 100 mg of hyoscine butylbromide each were found to be less than 1%.

Distribution

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

Following oral administration of single doses in the range of 100 to 400 mg, the terminal elimination half-lives ranged from 6.2 to 10.6 hours. The main metabolic pathway is the hydrolytic cleavage of the ester bond. Orally administered hyoscine butylbromide is excreted in the faeces and in the urine. Studies in man show that 2 to 5% of radioactive doses is eliminated renally after oral, and 0.7 to 1.6% after rectal administration. Approximately 90% of recovered radioactivity can be found in the faeces after oral administration. The urinary excretion of hyoscine butylbromide is less than 0.1% of the dose. The mean apparent oral clearances after oral doses of 100 to 400 mg range from 881 to 1420 L/min, whereas the corresponding volumes of distribution for the same range vary from 6.13 to 11.3 x 10⁵ L, probably due to very low systemic availability. 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.

Paracetamol BP

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract.

Distribution

Peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Biotransformation

It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdose and cause tissue damage.

Elimination

It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 hours

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.

Paracetamol found safe , not to be used below 10 years children.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

- Citric Acid BP
- Maize Starch BP
- PVPK-30 BP
- Magnesium Stearate BP
- Colloidal silicon Dioxide BP
- Crosscarmellose Sodium BP
- Pregelatinised Starch BP
- Instamoist Shield IC-MS- 2398
- Instaglow IH
- Isopropyl Alcohol BP
- Methylene Chloride BP

6.2 Incompatibilities:

None stated.

6.3 Shelf Life:

36 Months

6.4 Special precautions for Storage:

Store in a cool dry place below 30°C.

Keep medicines out of reach of children.

6.5 Nature and Contents of container

3 X 10 Tablet are packed in carton along with product insert.

7.0 Marketing Authorization Holder

Name: PHARMA LIFESCIENCE LTD.

2 nd Floor, Doctor's Park , 3 Parks Land

Nairobi , Kenya

P.O.BOX NO. 38148-00623,

email-id : Pharmalifescience@outlook.com

Telephone No: +254 722 839859

Manufacturing site address

Factory : Skybiotech Life Sciences Pvt. Ltd.

Address: Gut No. 5, Gevrai Tanda,

Paithan Road, Aurangabad (M.S) India.

Country : India

Telephone: (91) (240) 2694545

Telefax : (91) (240) 2694488

Email : aher.sr@yahoo.com

8. Marketing Authorization Numbers:

H2024/CTD8340/16387

9. Date of first registration /renewal of the registration:

22 May 2024

10. Date of revision of text:

Mar 19, 2026