

SPASMODEX-P

(Paracetamol & Hyoscine Butylbromide Tablets)

1.6.3 Patient information leaflet (PIL)

210.00 mm

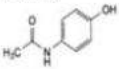
140.00 mm

For the use of Registered Medical Practitioners, Hospitals or laboratory only

SPASMODEX-P
Paracetamol and Hyoscine butylbromide tablets

Composition :
Each film coated tablet contains:
Paracetamol B.P. 500 mg
Hyoscine butyl bromide B.P. 10 mg
Colour : Titanium Dioxide B.P.

DESCRIPTION :
Paracetamol

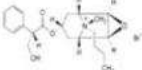

CC(=O)Nc1ccc(O)cc1

C8H9NO2 151.2 103-90-2
N-(4-Hydroxyphenyl) acetamide.

Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties and weak anti-inflammatory activity. Paracetamol is given by mouth or as a rectal suppository for mild to moderate pain and for fever. It may also be given by intravenous infusion for the short-term treatment of moderate pain, particularly following surgery, and fever. Paracetamol is often the analgesic or antipyretic of choice, especially in the elderly and in patients in whom salicylates or other NSAIDs are contra-indicated. Such patients include asthmatics, those with a history of peptic ulcer, and children.

ACTION AND USE :
Analgesic, antipyretic

Hyoscine Butylbromide


CCN(C)C1CC2C(C1)OC2C3C(C)C(C)C3

C21H30BrNO4 440.4 148-64-4
(1R,2R,4S,5S,7s,9r)-9-Butyl-7-[(2S)-3-hydroxy-2-phenylpropanoate]oxy]-9-methyl-3-oxa-8-azoniabicyclo[3.3.1]nonane bromide.

Hyoscine is a tertiary amine antimuscarinic with central and peripheral actions. It is a more powerful suppressant of salivation than atropine, and usually slows rather than increases heart rate, especially in low doses. Its central action differs from that of atropine in that it depresses the cerebral cortex and produces drowsiness and amnesia. Hyoscine hydrobromide is also a tertiary amine, whereas hyoscine butylbromide, hyoscine methobromide, and hyoscine methonitrate are quaternary ammonium derivatives.

Hyoscine and hyoscine hydrobromide are used in the management of motion sickness and other forms of nausea and vomiting. Hyoscine hydrobromide is also given as a premedicant in anaesthesia, and to produce mydriasis and cycloplegia. Hyoscine butylbromide and other quaternary ammonium derivatives are used in conditions associated with visceral spasms. In addition, hyoscine methobromide has been employed as an adjunct in the treatment of peptic ulcer disease. Other hyoscine salts or derivatives that have been used include hyoscine borate, hyoscine hydrochloride, and hyoscine oxide hydrobromide.

ACTION AND USE :
Anticholinergic.

PHARMACOLOGICAL PROPERTIES:
SPASMODEX-P tablets is a combination of hyoscine butyl bromide and paracetamol. Hyoscine butyl bromide is a quaternary ammonium derivative with antimuscarinic effects. It exerts a specific antispasmodic action on the smooth muscle of the gastrointestinal, biliary and urinary tracts, this action being produced long before the side-effects, characteristic of atropine-like substance occur. Paracetamol is a Para-aminophenol derivative, has analgesic and antipyretic properties. It is used in the symptomatic management of pain and fever.

PHARMACOKINETICS:
The quaternary derivatives (Hyoscine butyl bromide) are poorly absorbed from the gastrointestinal tract and do not readily pass the blood-brain-barrier. Hyoscine butyl bromide is almost entirely metabolized probably in the liver, only a small proportion of oral dose has been reported to be excreted unchanged in the urine. Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. It is distributed into most body tissues. It crosses the placenta and is present in breast milk. The administration half-life of the drug varies from about 1 to 3 hours. It is metabolized predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5 % is excreted as unchanged paracetamol.

USES :
Hyoscine butyl bromide Paracetamol is used for the treatment , control, prevention & improvement of the diseases, condition and symptoms of Toothache, Diarrhea, Headache, Ear pain, Joint Pain, Periods pain, Fever, Cold & Flu.

This is a combination of two medicines; Hyoscine butylbromide and Paracetamol , 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 is an analgesic (pain reliever) which works by blocking the release of certain chemical messengers that cause pain.

INDICATIONS:
Paroxysmal pain in diseases of stomach or intestine, spastic pain and functional disorders in the biliary and urinary tract and female genital organs.

CONTRAINDICATIONS:
Antimuscarinics (Hyoscine butylbromide included) are contraindicated in angle-closure glaucoma, myasthenia gravis (but may be used to decrease muscarinic side effects of acetylcholinesterases), paralytic ileus, pyloric stenosis and prostatic enlargement.

WARNING AND PRECAUTIONS:
SPASMODEX-P should be given with care in patients with impaired kidney or liver function in alcoholism and patients taking other drugs that affect the liver. Absorption of paracetamol content in SPASMODEX-P may be accelerated by metoclopramide. Excretion of paracetamol may be affected and plasma concentrations altered when administered with probenecid. SPASMODEX-P should be given with caution in patients with Myasthenia gravis, renal and hepatic impairment, diarrhea, glaucoma, hypertension, ulcerative colitis and down syndrome.

SIDE EFFECTS :
Gastrointestinal disturbances, staggering, skin rashes, conjunctivitis, anticholinergic side effects such as: dry mouth/skin, difficulty in swallowing, visual disturbances, flushings and drowsiness. Other adverse reactions include:- liver damage in prolonged use or over dosage.

DOSAGE AND ADMINISTRATION :
1 – 2 tablets 3 times daily.

PACKAGE:
Blister pack of 1 x 10's, 3 x 10's and 10 x 10's Packs.

STORAGE:
Store below 30°C. Protect from light and moisture .
Keep medicine out of reach of children.

Manufactured For :
Pharma Life Science Ltd.
P.O.Box. 38148-00623 Nairobi Kenya .

Manufactured By :
Skybiotech Life Sciences Private Limited,
Factory : Gut No: 5, Gevali Tanda, Palthan Road ,
Aurangabad-431002 (M S) India.