SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

Nospamin Syrup

2. Qualitative and quantitative composition

Each 5ml contains Homatropine Methylbromide 5mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup.
A pinkish syrup liquid with a mint flavour. .

4. Clinical particulars

4.1 Therapeutic indications

Nospamin Syrup is used in the treatment of gastro intestinal spasms and as an adjunct in the treatment of peptic ulcer.

4.2 Posology and method of administration

Children

1 – 3 years: 2.5ml 2 to 3 times daily

4 – 6 years: 5ml 2 to 3 times daily

6 – 12 years: 5-10ml 2 to 3 times daily

Method of Administration

Oral administration only

4.3 Contraindications

Nospamin syrup may increase the rate of metabolism of other drugs such as folic acid, griseofulvin and anti-coagulants of the coumarin type and care should be taken when concomitant administration of Nospamin syrup and these other drugs are inevitable. Nospamin syrup should also be given with caution to patients with impaired kidney or liver function and to patients taking other drugs that affect the liver.

4.4 Special warnings and precautions for use

Nospamin Syrup should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal functions, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture, asthma, and narrow-angle glaucoma.

4.5 Interaction with other medicinal products and other forms of interaction

Acetazolamide may increase the central nervous system depressant (CNS depressant) activities of Homatropine methylbromide.

The risk or severity of adverse effects can be increased when Homatropine methylbromide is combined with Aclidinium

The risk or severity of Tachycardia can be increased when Adenosine is combined with Homatropine methylbromide.

4.6 Pregnancy and Lactation

Pregnancy

Homatropine methylbromide use in pregnancy is not recommended
Prolonged use of opioids during pregnancy may cause neonatal withdrawal syndrome and physical dependence in the neonate.

Lactation

Excreted into human milk is unknown

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The adverse effects of Nospamin syrup may include dryness of mouth with difficulty in swallowing, thirst, reduction in the tone and motility of the gastro-intestinal tract leading to constipation, nausea, vomiting, skin rashes and other allergic reactions may occur occasionally.

4.9 Overdose

Over dosage may also cause abnormalities of glucose metabolism and metabolic acidosis. Postural hypotension, changes in patients mental conditions such as loss of memory, inability to concentrate, giddiness, depression and dullness of mental perception may also occur as a result of prolonged over dosage.

Treatment

In the event of over dosage the stomach should be emptied by aspiration and lavage. The patient should be carefully nursed and oxygen administered if necessary as supportive therapy.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Homatropine Methylbromide is the methylbromide salt of homatropine, a synthetic tertiary amine alkaloid with antimuscarinic properties. Homatropine methylbromide, a competitive inhibitor of acetylcholine at the muscarinic receptor, blocks parasympathetic nerve stimulation, thereby inhibiting pepsin and gastrin secretion. When administered in high doses, this drug produces inhibitory effects on acetylcholine activity, specifically on smooth muscle located in the gastrointestinal, biliary, and genitourinary tracts, resulting in an anti-spasmodic effect.

Mechanism of action

Homatropine is a quaternary ammonium muscarinic acetylcholine receptor antagonist. The muscarinic acetylcholine receptor mediates various cellular responses, including inhibition of adenylate cyclase, breakdown of phosphoinositides and modulation of potassium channels through the action of G proteins. Homatropine methylbromide inhibits the muscarinic actions of acetylcholine on structures innervated by postganglionic cholinergic nerves as well as on smooth muscles that respond to acetylcholine but lack cholinergic innervation. These postganglionic receptor sites are present in the autonomic effector cells of the smooth muscle, cardiac muscle, sinoatrial and atrioventricular nodes, and exocrine glands. Depending on the dose, anticholinergics may reduce the motility and secretory activity of the gastrointestinal system, and the tone of the ureter and urinary bladder and may have a slight relaxant action on the bile ducts and gallbladder.

5.2 Pharmacokinetic properties

Nospamin is readily absorbed from the gastro-intestinal tract and mucous membranes. It disappears rapidly from the blood and is distributed throughout the body. It is excreted in the urine.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical particulars

6.1 List of excipients

Methyl paraben

Propyl paraben
Sugar
Citric acid
Sodium citrate
Allura red colour
Sorbitol(70% solution)
Peppermint oil
Tutti fruitti flavour
Alcohol
Sodium CMC:
Bronopol
Sodium saccharine

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 30 ° C.

6.5 Nature and contents of container

Nospamin Syrup is packaged in Amber PET bottle of 60ml

6.6 Special precautions for disposal and other handling

No special requirements for disposal

7. APPLICANT/MANUFACTURER

Afrab Chem Limited
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