DUXCOSPAN

Duxcospan

Composition: Duxcospan syrup :

Each 5 ml contains Hyoscine Butylbromide B.P..... 5mg .

Duycosnan tablets

Each film coated tablet contains Hyoscine Butylbromide B.P.....10 mg.

Each sugar coated tablet contains Hyoscine Butylbromide B.P..... 10 mg.

Properties:

Duxcospan exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genito-urinary tracts. As a quarternary ammonium additive, Hyoscine N-butylbromide does not enter the central nervous system. Therefore anticholinergic effects at the central nervous system do not occur. Peripheral anticholinergic action results from ganglion- blocking action within the visceral wall as well as from the anti-muscarinic activity.

Pharmacokinetics:

As a quaternary ammonium compound, Hyoscine-N- butylbromide is highly polar and hence only partially absorbed following oral(8%) or rectal (3%) administration. The systemic availability was found to be less than 1% Nevertheless, despite the briefly measurable low blood vessels, relatively high local concentrations of radio-labelled hyoscine-N-butylbromide and/or its metabolites have been observed at the site of action: in the gastro intestinal tract, gall bladder, bile ducts, liver and kidneys. Hyoscine-N-butylformide does not pass the blood-brain barrier and its binding to plasma protein is low. The total clearnined after i.v administration, is 1.21/min, approximately half of the clearance is renal. The main metabolites found in urine bind poorly to the muscarinic receptor. Indications :

Gastrointestinal tract spasm, spasm and dyskinesia of the biliary system, genital urinary tract spasm.

Contraindications

DUXCOSPAN is contraindicated in myasthenia gravis and megacolon. In addition, it should not be used in patients who have demonstrated prior sensitivity to hvoscine-N-butylbromide or any other component of the product.

Interaction:

Anticholinergic effects of tricvclic antidepressants, antihistamines, quinidine, amantadine and disopyramide may be intensified by DUXCOSPAN. 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 DUXCOSPAN.

Side effects:

Anticholinergic side effects including xerostomia, dyshidrosis, tachycardia and potentially urinary retention may occur but are generally mild and self limited. Very rarely hypersensitivity reactions, particularly skin reactions and in extremely rare cases, dysponea have been reported.

Special Precautions :

Because of the potential risk in Anticholinergic complications caution should be used with patients prone to narrow angle glaucoma as well as in patients susceptible to intestinal or urinary outlet obstruction and in those inclined to tachvarrhythmia.

Dosage and administration:

Unless otherwise prescribed by the physician ,the following dosages are recommended:

Dosage and Administration:

Duxcospan Syrup:

Children 1-3 years: 2.5 ml three times daily

Children 3-5 years: 5 ml three times daily Children 6-12 years: 10 ml three times daily

Duycosnan Tablets

Adults and children over 6 years:

1-2 tablets 3 to 5 times a day.

The tablets should be swallowed whole with adequate fluid .

Overdose:

Since cases of poisoning with DUXCOSPAN have not been reported so far, the following recommedations are based on theorotical consideratons.

Symptoms

In case of over dosage ,anticholinergic symptoms as urinary retention ,dry mouth ,reddening of the skin ,tachycardia,inhibition of gastrointestinal motility, and transient visual disturbance may occur.

Therapy

In case of oral poisoning, gastric lavage with medicinal charcoal should be followed by magnesium sulfate(15%), Symptoms of DUXCOSPAN over dosage respond to parasympathomimetics. For patients with glaucoma, pilocarpine should be given locally. If necessary, parasympathomimetics should be administered, e.g. Neostigmine 0.5-2.5mg i.m or i.v. Cardiovascular complications should be treated according to usual therapeutic principles. In case of respiratory paralysis: intubation, artificial respiration. Catheterization may be required for urinary retention. In addition, appropriate supportive measures should be used as required. Presentation

Syrup:

Available in 60ml and 100ml in amber colored bottles and 5litres in plastic jerrycans.

Tablets.

Blister packs of 10's & 100's in unit boxes and 100's, 500's and 1000's in plastic containers.

Storage:

Do not store above 30ºC. Store in a dry place. Protect from direct sunlight. Keep all medicines out of reach of children.

Manufactured by:



Z/PLLE00039/X/001