SCHEDULING STATUS:

S2

PROPRIETARY NAME (AND DOSAGE FORM):

DICYCLOMINE CO GEL

COMPOSITION:

Each 10 ml of suspension contains:

Dicyclomine Hydrochloride: 5 mg

Compressed Aluminium Hydroxide Gel: 400 mg

(equivalent to Dried Aluminium Hydroxide)

Light Magnesium Oxide: 200 mg

Preservative:

Nipastat: 0,2 % *m/v*

Contains:

Benzyl Alcohol: 0,3 % *v/v*

PHARMACOLOGICAL CLASSIFICATION:

Category A 11.4.2 Acid Neutralisers with antispasmodics (preventing or relieving convulsions or spasms).

PHARMACOLOGICAL ACTION:

DICYCLOMINE CO GEL has antacid (neutralises the acid) properties.

INDICATIONS:

DICYCLOMINE CO GEL is indicated as an antacid. (Neutralises the acid).

CONTRA-INDICATIONS:

Prostatic (prostate gland) enlargement, paralytic ileus (loss of voluntary muscle movement in the intestines) or

pyloric stenosis (narrowing of the muscular tissue controlling the outlet of the stomach) where its use may

lead to obstruction, severe ulcerative colitis (disease affecting the colon/ large intestine), myasthenia gravis
(muscle disorder causing weakness), glaucoma (raised pressure in the eye). Patients with renal (kidney)
failure. Obstructive uropathy (any disorder involving the urinary tract), thyrotoxicosis (overactive thyroid),
cardiac failure. Sensitivity to any of the ingredients.

WARNINGS:

DICYCLOMINE CO GEL should be used with caution in conditions characterised by tachycardia (increase rate of heart beat) such as thyrotoxicosis (overactive thyroid) and cardiac insufficiency or failure.

Do not use this product in infantile colic.

DOSAGE AND DIRECTIONS FOR USE:

Adults: 10 to 20 ml three to four times daily.

Children over 2 years of age: 5 to 10 ml three to four times daily.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects that may occur because of the dicyclomine include dry mouth, blurred vision, flushing and dryness of skin, tachycardia (increased rate of heart beat) with palpitations (rapid irregular actions of the heart) and arrhythmias (irregular heart beat), urinary retention and constipation (infrequent bowel movement). Its effects may be enhanced by other drugs with anticholinergic (to stop the passage of certain nerve impulses involving acetyl choline) properties. Fatigue, sedation (relaxing/calming effect), rash, thirst, nausea (the feeling that one is about to vomit) and vomiting, headache and dizziness have been reported.

Preparations containing dicyclomine should be used with caution in elderly men.

5 - 10 % of magnesium is absorbed and retention in patients with impaired renal function (decreased function of the kidney) may lead to neurological (disorder of the nervous system), neuromuscular (relationship between the nerve and muscle) and cardiovascular

(heart and blood vessels) impairment. The urine of normal persons may become alkaline which decreases excretion of drugs which are weak bases. Magnesium may cause diarrhoea (frequent or loose watery stools) and mucosa! (moist lining of body cavities) irritation. Aluminium hydroxide absorbs phosphates and excessive doses or normal doses with a low phosphate diet may lead to phosphate depletion with renal (kidney) rickets or osteomalacia (a disease characterised by a gradual and painful softening and bending of the bones). Use with care in patients with hiatal hernia (protrusion of a part
of the stomach through the diaphragm) associated with reflux oesophagi tis (inflammation of the oesophagus)
because anticholinergic (stop the passage of certain nerve impulses involving acetyl choline) drugs may aggravate the condition. DICYCLOMINE CO GEL may interfere with or reduce the absorption of
anticholinergic (stop the passage of certain nerve impulses involving acetyl choline) medicines, barbiturates, digoxin, quinine, quinidine, warfarin tetracyclines and vitamins. The effects of dicyclomine hydroxide may be enhanced by the concomitant administration of anticholinergic
(stops the passage of ce1tain nerve impulses involving acetyl choline) medicines such as antihistamines (medicines used to prevent or relieve symptoms of some types of allergies such as hayfever and runny nose)
amantidine, butyrophenones, phenothiazine and tricyclic antidepressants.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:

Toxic doses of dicyclomine cause tachycardia (increased rate of heart beat), rapid or stenorous (shallow) respiration (breathing), hyperpyrexia (abnormally high body temperature), restlessness, confusion and
excitement, and hallucinations (false perceptions) passing into delirium (rapid succession of confused and unconnected ideas often with illusions and hallucinations). A rash may appear on the face and upper trunk. In severe intoxication, depression of the central nervous

system may occur with hypertension (high blood pressure) 01· circulatory failure and respiratory depression (abnormally slow and/or shallow breathing).

TREATMENT:

See further under side-effects and "Side-effects and Special Precautions". Treatment is symptomatic and supportive.

IDENTIFICATION:

A white homogenous suspension with a slight peppermint flavour.

PRESENTATION:

100 ml, 200 ml and 2,5 litre amber or white plastic bottles.

STORAGE INSTRUCTIONS:

Store in a cool place, below 25°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

E 1405 (Act101 of 1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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