

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dicycloverine Hydrochloride 20mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dicycloverine hydrochloride 20mg

Excipients with known effect

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets

Dicycloverine hydrochloride 20mg tablets are white, Oval circular shaped, biconvex, uncoated tablets debossed with 'D' on one side and '2' on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Smooth muscle antispasmodic primarily indicated for treatment of functional conditions involving smooth muscle spasm of the gastrointestinal tract.

4.2 Posology and method of administration

Posology

Adults and children over 12 years:

1 Tablet three times daily before or after meals.

Method of administration

Oral

4.3 Contraindications

Hypersensitivity to dicycloverine hydrochloride or any of the excipients listed in section 6.1

Known idiosyncrasy to dicycloverine hydrochloride.

4.4 Special warnings and precautions for use

Products containing dicycloverine hydrochloride should be used with caution in any patient with or suspected of having glaucoma or prostatic hypertrophy. Use with care in patients with hiatus hernia associated with reflux oesophagitis because anticholinergic drugs may aggravate the condition.

Patients with rare hereditary problems of fructose intolerance, sucrase-isomaltase insufficiency, galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Epidemiological studies in pregnant women with products containing dicycloverine hydrochloride (at doses up to 40mg/day) have not shown that dicycloverine hydrochloride increases the risk of foetal abnormalities if administered during the first trimester of pregnancy.

Breast-feeding

It is not known whether dicycloverine is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dicycloverine is administered during breast-feeding.

Fertility

Reproduction studies have been performed in rats and rabbits at doses of up to 100 times the maximum recommended dose (based on 60mg per day for an adult person) and have revealed no evidence of impaired fertility or harm to the foetus due to dicycloverine hydrochloride. Since the risk of teratogenicity cannot be excluded with absolute certainty for any product, the drug should be used during pregnancy only if the benefit outweighs the risk.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side-effects seldom occur with dicycloverine tablets. However, in susceptible individuals, dry mouth, thirst and dizziness may occur. On rare occasions, fatigue, sedation, blurred vision, rash, constipation, anorexia, nausea and vomiting, headache and dysuria have also been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard Or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of dicycloverine overdosage are headache, dizziness, nausea, dry mouth, difficulty in swallowing, dilated pupils and hot dry skin. Treatment may include emetics, gastric lavage and symptomatic therapy if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Synthetic anticholinergics, esters with tertiary amino group,

ATC Code: A03AA07

Dicycloverine hydrochloride relieves smooth muscle spasm of the gastrointestinal tract.

Animal studies indicate that this action is achieved via a dual mechanism;

- (1) a specific anticholinergic effect (antimuscarinic at the ACh-receptor sites) and
- (2) a direct effect upon smooth muscle (musculotropic).

5.2 Pharmacokinetic properties

After a single oral 20mg dose of dicycloverine hydrochloride in volunteers, peak plasma concentration reached a mean value of 58ng/ml in 1 to 1.5 hours. ¹⁴C labelled studies demonstrated comparable bioavailability from oral and intravenous administration. The principal route of elimination is via the urine.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate

Calcium Hydrogen Phosphate Anhydrous

Maize Starch

Sucrose

Sodium Starch Glycolate (Type A)

Liquid Glucose

Magnesium Stearate

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Dicycloverine Hydrochloride 20 mg Tablets are packed in blister packs comprised of aluminum foil (20 µm) with PVC white opaque film (250 µm) blisters.

Pack size: 84, 100 tablets

Not all pack sizes are marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Noumed Life Sciences Limited
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8 MARKETING AUTHORISATION NUMBER(S)

PL 44041/0129

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/06/2024

10 DATE OF REVISION OF THE TEXT

03/06/2024