SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dicycloverine Hydrocloride 10 mg/5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dicycloverine Hydrocloride 10 mg/5 ml: One ml contains 2 mg dicycloverine hydrochloride.

Excipient with known effect
Each ml of oral solution contains 968.3 mg of glucose, 1.4 mg of ethanol, 0.13 mg of sodium, 1.4 mg of propylene glycol, and 0.8 mg of sodium benzoate (see section 4.4).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

The oral solution is clear, slightly brownish-yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dicycloverine is a smooth muscle antispasmodic primarily indicated for treatment of functional conditions involving smooth muscle spasm of the gastrointestinal tract. The commonest of these are irritable colon (mucous colitis, spastic colon).

4.2 Posology and method of administration

Posology

Adults

5-10 ml (10-20 mg) three times daily before or after meals.

Children (2-12 years):

5 ml (10 mg) three times daily.

Children (6 months-2 years)

2.5-5 ml (5-10 mg) three or four times daily, 15 minutes before feeds. Do not exceed a daily dose of 20 ml (40 mg). If it is necessary to dilute /…/ this may be done if diluted immediately prior to use with water.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Known idiosyncrasy to dicycloverine hydrochloride.

Infants under 6 months of age.

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. There are reports of infants, 3 months of age and under, administered dicycloverine hydrochloride syrup who have evidenced respiratory symptoms (breathing difficulty, shortness of breath, breathlessness, respiratory collapse, apnoea) as well as seizures, syncope, asphyxia, pulse rate fluctuations, muscular hypotonia and coma. The above symptoms have occurred within minutes of ingestion and lasted 20-30 minutes. The symptoms were reported in association with dicycloverine hydrochloride syrup therapy but the cause and effect relationship has neither been disproved or proved. The timing and nature of the reactions suggest that they were a consequence of local irritation and/or aspiration, rather than to a direct pharmacological effect. Although no causal relationship between these effects, observed in infants and dicycloverine administration has been established, dicycloverine hydrochloride is contra-indicated in infants under 6 months of age.

This medicinal product contains glucose, ethanol, sodium, propylene glycol and sodium benzoate.

Glucose
Patients with rare glucose-galactose malabsorption should not take this medicine. May be harmful to the teeth.

Ethanol
This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

Sodium
This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dosage unit, that is

to say essentially ‘sodium-free’.

Propylene glycol
This medicine contains 7 mg propylene glycol in each 5 ml dosage unit which is equivalent to 1.4 mg/ml.

Sodium benzoate
This medicine contains 4 mg benzoate salt in each 5 ml dosage unit which is equivalent to 0.8 mg/ml.

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 40 mg/day) have not shown that dicycloverine hydrochloride increases the risk of fetal abnormalities if administered during the first trimester of pregnancy. 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.

Breastfeeding
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
Animal studies in rats and rabbits reveal no evidence of impaired fertility (see section 5.3). The effect on fertility with dicycloverine hydrochloride in humans is unknown.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side-effects seldom occur with dicycloverine. 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: Drugs for functional gastrointestinal disorders, Synthetic anticholinergics, ester 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;

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

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and carcinogenic potential.

Reproduction studies have been performed in rats and rabbits at doses of up to 100 times the maximum recommended dose (based on 60 mg per day for an adult person) and have revealed no evidence of impaired fertility or harm to the fetus due to dicycloverine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose liquid
Citric acid monohydrate (E330)
Sodium benzoate (E211)
Cherry flavour (contains ethanol and propylene glycol)
Raspberry flavour (contains ethanol and propylene glycol)
Blackcurrant flavour (contains propylene glycol)
Vanilla flavour (contains ethanol and propylene glycol)
Water, purified

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years

Shelf life after first opening: 6 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

Type III, EP amber glass bottles closed with child resistant screw caps with a polyethylene adaptor containing 120 ml per bottle.

Each carton contains 1 bottle and a calibrated PP 10 ml measuring syringe with HDPE plunger. The syringe is scaled at 0.5 ml.

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

Teva UK Limited
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Whistler Drive,
Castleford,
WF10 5HX,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2227

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/11/2018

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30/09/2021