SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dicycloverine hydrochloride 20 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 mg dicycloverine hydrochloride

Excipient with known effect:
Each 20 mg tablet contains lactose monohydrate 129.00 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Each 20 mg tablet is a round, white, biconvex tablet, 8 mm in diameter, 3.60 mm in thickness, marked with A203 on one side.

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
20 mg dicycloverine hydrochloride three times daily.

Method of administration

Oral use.
The tablets should be taken before or after meals.

4.3 Contraindications

Hypersensitivity to the active substance or to 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.

The tablets contain lactose. Patients with rare hereditary problems of 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 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 to a nursing mother.

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 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: 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;

(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 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 foetus due to dicycloverine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Cellulose, microcrystalline
Starch, pregelatinised (maize)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

[PVC/Al blisters]:
18 months

[PVC/PVdC/Al blisters] and [PVC/PVdC/PVC (amber)/Al blisters]:
2 years

6.4 Special precautions for storage

[PVC/Al blisters]:
Do not store above 25°C

[PVC/PVdC/Al blisters] and [PVC/PVdC/PVC (amber)/Al blisters]:
This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

PVC/Al blisters, PVC/PVdC/Al blisters and PVC/PVdC/PVC (amber)/Al blisters:

Pack size: 84 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Teva UK Limited.
Ridings Point,
Whistler Drive,
Castleford,
WF10 5HX,
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2163

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/08/2018

10 DATE OF REVISION OF THE TEXT

18/10/2021