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 of Dicycloverine hydrochloride.

Excipient(s) with known effect:

Each tablet contains 134.00 mg lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White to off white, circular, flat beveled edge uncoated tablet debossed with “S” and “20” separated by break-line on one side and plain on other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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 a day before or after meals

Method of administration

Oral

4.3 Contraindications

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

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.

Dicycloverine hydrochloride 20 mg Tablets contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp 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 foetal abnormalities if administered during the first trimester of pregnancy.

Fertility:

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. Since the risk of teratogenicity cannot be excluded with absolute certainty for any product, the drug should be used during pregnancy only if clearly needed.

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 to a nursing mother.

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 Yellow Card Scheme at: 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, 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 20 mg dose of dicycloverine hydrochloride in volunteers, peak plasma concentration reached a mean value of 58ng/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

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Maize starch

Povidone

Purified talc

Colloidal anhydrous silica

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 available in cartons containing Aluminium-PVC/PVDC White opaque blister packs of 84's, 100's along with a leaflet inside.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.

Ist floor, Kirkland House,

11-15 Peterborough Road,

Harrow, Middlesex,

HA1 2AX, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0042

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/10/2018

10 DATE OF REVISION OF THE TEXT

30/01/2020