SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<Trade Name> <Strength> tablets

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contain 20 mg of dicycloverine hydrochloride

Excipient(s) with known effect:

<Regarding the approval>

For a full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Tablets

<Regarding the approval>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

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

* 1. 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

* 1. Contraindications

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

Known idiosyncrasy to dicycloverine hydrochloride.

* 1. 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 contains lactose, sucrose and glucose.

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

* 1. Interaction with other medicinal products and other forms of interaction

None stated.

* 1. 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 60 mg 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.

* 1. Effects on ability to drive and use machines

None stated.

* 1. 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 Health Product Vigilance Center; HPVC, Thai FDA.

* 1. 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.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

*Pharmacotherapeutic group:*

Drugs for functional gastrointestinal disorders, 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).

* 1. Pharmacokinetic properties

Distribution and Biotransformation

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.

14C labelled studies demonstrated comparable bioavailability from oral and intravenous administration.

Elimination

The principal route of elimination is via the urine.

* 1. Preclinical safety data

None stated.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<Regarding the approval>

* 1. Incompatibilities

<Regarding the approval>

* 1. Shelf life

<Regarding the approval>

* 1. Special precautions for storage

<Regarding the approval>

* 1. Nature and contents of container

<Regarding the approval>

* 1. Special precautions for disposal

<Regarding the approval>

1. MARKETING AUTHORISATION HOLDER

<Regarding the approval>

1. MARKETING AUTHORISATION NUMBER(S)

<Regarding the approval>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Regarding the approval>

1. DATE OF REVISION OF THE TEXT1

<Regarding the approval>