Summary of Product Characteristics

1. Name of the medicinal product

Notensyl Tablets

2. Qualitative and quantitative composition

Each tablet of Notensyl contains Dicyclomine hydrochloride 10mg

3. Pharmaceutical form

Tablets

4. Clinical particulars

4.1 Therapeutic indications

Adjunctive therapy in irritable bowel syndrome, neurogenic bowel disturbance

4.2 Posology and method of administration

Route of administration: Oral
Adolescents and Adults (above 12 years): 10-20mg three times daily before or after meals.
Children (2-12 years): 10mg three times daily.
Do not exceed a daily dose of 40mg.

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 dicyclomine 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.

Notensyl Tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucosegalactose 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

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

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

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side-effects seldom occur with dicyclomine. 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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

4.9 Overdose

Symptoms of dicyclomine 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, ATC code: A03AA07
Dicyclomine 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 dicyclomine 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, Maize Starch, Povidone, Magnesium Stearate, Sorbitol Solution 70%
6.2 Incompatibilities
None stated.
6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.
6.4 Special precautions for storage
Do not store above 25°C.
6.5 Nature and contents of container
Blisters packs contains biconvex white tablet, 10 tablets per one blister. Pack size: 20 tablets

7. Marketing authorisation holder
CTS Chemical Industries Ltd.
Hakidma 3, Kiryat-Malachi
Israel

8. Marketing authorisation number(s)
1178523254

9. Date of revision of the text
Revised in 05 2021 according to MOHs guidelines