Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dicycloverine hydrochloride 10mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dicycloverine Hydrochloride Oral Solution contains the active ingredient, dicycloverine hydrochloride.

Each 5ml solution contains 10mg dicycloverine hydrochloride.

Excipients with known effect:
Each 5ml solution contains 14.735mg of propylene glycol (E1520), 4mg of sodium benzoate and 3.696g of mixture of fructose, glucose and sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution
Clear, light yellow to yellow solution with a strawberry flavour

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Dicycloverine Hydrochloride 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 (mucouscolitis, spastic colon).

4.2 Posology and method of administration

Adults
One to two 5ml spoonfuls (10-20mg) three times daily before or after meals.

Children (2-12 years):
One 5ml spoonful (10mg) three times daily.

Children (6 months - 2 years)
5-10mg three or four times daily 15 minutes before feeds. Do not exceed a daily dose of 40mg.

Dicycloverine Hydrochloride is contraindicated in children under 6 months of age (see sections 4.3 and 4.4).

Method of administration:
For oral administration.
If it is necessary to dilute Dicycloverine Hydrochloride Oral Solution, this may be done using syrup or if diluted immediately prior to use with water.

4.3 Contraindications

Hypersensitivity to dicycloverine hydrochloride or 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.

Excipient(s) warning:
This medicine contains invert sugar. Patients with rare hereditary fructose intolerance (HFI), glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicinal product. May be harmful to the teeth, if the medicine is intended for use for two weeks or more.

This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interactions

None reported.

4.6 Fertility, pregnancy and lactation

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. 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 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.

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.

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 HPRA Pharmacovigilance Website: www.hpra.ie.

4.9 Overdose

Symptoms of dicycloverine hydrochloride over dosage 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

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 20mg dose of dicycloverine hydrochloride in volunteers, peak plasma concentration reached a mean value of 58ng/mlin 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

Citric acid monohydrate(E330)
Sucralose(E955)
Invert syrup(contains glucose, sucrose and fructose)
Sodium benzoate(E211)
Strawberry flavour (contains propyleneglycol(E1520) and natural flavouring substances)
Purified water

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Bottle: Amber glass
Closure: HDPE, EPE wadded, tamper evident, child resistant screw on white plastic polypropylene cap.
Dosing Device: Double ended plastic spoon with 2.5ml and 5ml measuring ends
Packsize: 100ml, 120ml, and 300ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal products or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Syri Pharma Limited t/a Thame Laboratories
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1 WML
1 Windmill Lane
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8 MARKETING AUTHORISATION NUMBER

PA22697/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th January 2015
Date of Last Renewal: 15th December 2019

10 DATE OF REVISION OF THE TEXT

December 2020