Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Medithyme Cough Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml of syrup contains 0.98 g of liquid extract from *Thymus vulgaris* L., herba (Thyme herb) (1 : 2-3).
Extraction solvent: ammonia 10 % m/m, glycerol 85 % m/m, ethanol 90 % v/v, water (1/20/70/109).
The maximum daily dose of 60 ml contains: ethanol 1.04 g, maltitol 66.30 g, potassium 14.2 mg, sodium benzoate 78 mg and sodium 24.64 mg (1.092 mmol).
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup
Straw-yellow, sweet molasses with the taste and the odour of thyme.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Medithyme Cough Syrup is a traditional herbal medicinal product used as an expectorant in productive cough associated with cold.
It is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.
Medithyme Cough Syrup is indicated in adults and adolescents aged 12 years and over.

4.2 Posology and method of administration

Posology
Children from 12 years and adults: 15 ml, 4 times per day.

The interval between two intakes should be at least 4 hours.
The use in children under 12 years of age is not recommended (see 4.4: Special warnings and precautions for use).
If the symptoms persist, worsen or do not improve after one weeks use of Medithyme Cough Syrup, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

Method of administration
For oral short-term use only.

4.3 Contraindications

Hypersensitivity to thyme or to other members of the Lamiaceae (mint) family, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

The use in children under 12 years of age is not recommended because medical advice should be sought.
Do not exceed the stated dose.
When dyspnoea, fever or purulent sputum occurs, a doctor should be consulted.
If the symptoms worsen during the use of this medicine, a doctor should be consulted.
This medicine contains 260 mg of alcohol (ethanol) in each dose (15 ml), which is equivalent to 2.2 % vol ethanol (alcohol). The amount in each dose (15 ml) of this medicine is equivalent to less than 7 ml beer or 3 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
This medicine contains liquid maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Maltitol may have a mild laxative effect. Calorific value: 2.3 kcal/g maltitol.
This traditional herbal medicine contains 19.5 mg benzoate salt in each 15 ml dose.

This traditional herbal medicine contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Patients who are treated with medicines known to interact with alcohol such as disulfiram or metronidazole should avoid this traditional herbal medicine because of the presence of ethanol in thyme liquid extract.
The concomitant use of multiple medicines that contain ethanol should be avoided.

4.6 Fertility, pregnancy and lactation

Pregnancy and breast-feeding
Safety of the use of Medithyme Cough Syrup during pregnancy and lactation has not been established. In the absence of sufficient data, the use of Medithyme Cough Syrup during pregnancy and lactation is not recommended.

Fertility
Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.
It should be kept in mind that Medithyme Cough Syrup contains 2.2% (v/v) alcohol.

4.8 Undesirable effects

- Acute hypersensitivity reactions (including anaphylactoid reactions, such as oromucosal swelling, Quincke's oedema, dyspnoea, pruritus, rash and anaphylactic shock) have been reported in association with use of herbal medicinal products containing thyme, in some cases, in patients with a history of allergy/asthma.
- Gastric disorders may occur. The frequency is not known.

If these or other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

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 national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Not applicable. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

An Ames test conducted with Thyme liquid extract demonstrated no mutagenic effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, anhydrous
Sodium benzoate E 211
Potassium sorbate
Sodium citrate dihydrate
Liquid maltitol E 965
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years
Use within 6 months of opening.

6.4 Special precautions for storage

This medical product does not require any special storage conditions.

6.5 Nature and contents of container

Glass bottle of 125 ml or 180 ml syrup with child-resistant closure of polypropylene with a polyethylene sealing disk, delivered with a cup of 30 ml.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR0126/319/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 15th January 2021
Date of last renewal: 02nd May 2025

10 DATE OF REVISION OF THE TEXT

May 2025