Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Herbal Dry Cough Pastilles

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pastille contains
10 mg dry extract from *Sisymbrium officinale* (L.) Scop., herba (hedge mustard herb) (DER 6-8:1), extraction solvent: water.

Excipients with known effect:
- maltitol: 441 mg / pastille
- sorbitol: 100 mg / pastille
- Fragrance containing allergen (Cinnamal)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Pastille
Brownish, round pastille of 16 mm diameter

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Strepsils Herbal Dry Cough Pastilles is a traditional herbal medicinal product used for the relief of the symptoms of throat irritation such as hoarseness and dry cough, exclusively based upon long-standing use.

Strepsils Herbal Dry Cough Pastilles is indicated in adults and adolescents aged 12 years and older.

4.2 Posology and method of administration

Posology

Adults, elderly and adolescents from 12 years of age: 1 pastille 10-12 times a day

Paediatric population
Children under 12 years of age: The use in children younger than 12 years is not recommended due to the lack of adequate data (See section 4.4).

Patients with impaired liver or kidney function
Sufficient data is not available to define a recommended dose for patients with impaired liver or kidney function. Therefore, the use of Strepsils Herbal Dry Cough Pastilles is not recommended in these patient groups.

Method of administration

Oromucosal use
Pastille to dissolve in the mouth without chewing.
Duration of use
If the symptoms persist, worsen or do not improve after 7 days during the use of Strepsils Herbal Dry Cough Pastilles, a qualified healthcare professional e.g. doctor or a pharmacist should be consulted.

For oral short-term use only.

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

Do not exceed the stated dose.

If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.

If dyspnoea, fever or purulent sputum occurs, a doctor should be consulted immediately.

Paediatric population
The use in children under 12 years of age is not recommended because data are insufficient and medical advice should be sought.

This medicine contains fragrance with Cinnamal. Cinnamal may cause allergic reactions.

This medicine contains 441 mg of maltitol liquid and 100.0 mg of sorbitol liquid in each pastille. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicine. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies with Strepsils Herbal Dry Cough Pastilles and other medicinal products have not been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of hedge mustard herb in pregnant women. Animal studies are insufficient with respect to developmental toxicity. Strepsils Herbal Dry Cough Pastilles is not recommended during pregnancy.

Breast-feeding
It is unknown whether the active substance or its metabolites are excreted into human breast milk. A risk to the breastfed newborn / child cannot be excluded. Strepsils Herbal Dry Cough Pastilles should not be used during breast-feeding.

Fertility
There are no data on the effects on fertility available.

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.

4.8 Undesirable effects

None known.
If adverse reactions occur, a doctor or a pharmacist should be consulted.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after registration 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. See HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

Notrequired as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

In an in-vitro bacterial reverse mutation test (Ames test) on 5 Salmonella typhimurium strains, no relevant mutagenic potential of dry extract from Sisymbrium officinale, herba (75%native, DERnative 6-8:1, extraction solvent: water) has been detected.
Studies on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltodextrin
Maltitol liquid (E965)
Acacia (Gum Arabic) (E414)
Sorbitol liquid (non-crystallising) (E420)
Triglycerides medium-chain
Sucralose (E955)
Purified water
Honey-Lemon- Verveine flavour (flavour contains Cinnamal)
Maize starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

Brownish, round pastilles in aluminium/PVC/PE/PVDC blisters. The blisters are packed in cartons.
One package contains 10, 12, 20, 24, 30, 36, 40 or 48 pastilles.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 REGISTRATION HOLDER

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8 REGISTRATION NUMBER(S)

TR0979/089/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 27th February 2026

10 DATE OF REVISION OF THE TEXT

February 2026