

SUMMARY OF PRODUCT CHARACTERISTICS

1) NAME OF THE MEDICINAL PRODUCT

CHOPHYTOL 20 PER CENT, oral solution

2) QUALITATIVE AND QUANTITATIVE COMPOSITION

Soft aqueous artichoke extract..... 20.000 g

For 100 ml of oral solution.

Alcoholic degree = 3.23° (V/V).

Each teaspoon contains 0.13 g of absolute alcohol.

For a full list of excipients, see section 6.1.

3) PHARMACEUTICAL FORM

Oral solution.

4) CLINICAL PARTICULARS

4.1. Therapeutic indications

Traditionally indicated to improve the renal and digestive elimination functions.

4.2. Posology and method of administration

FOR ADULTS ONLY.

Oral use.

Swallow 1 teaspoon with water before the 3 main meals or when symptoms occur.

4.3. Contraindications

Not specified.

4.4. Special warnings and precautions for use

Do not administer in case of bile tract obstruction and severe hepato-cellular insufficiency.

Take into account the content of alcohol (0.13 g by teaspoon) and avoid intake of alcoholic beverages.

4.5. Interactions with other products and other forms of interaction

Concomitant use to be taken into account

Due to the alcohol content (0.13 g/teaspoon):

+ **Medicinal products inducing antabuse reaction with alcohol (warmth, blush, vomiting, tachycardia)**

Disulfirame, cefamandole, cefoperazone, latamoxef (cephalosporin antibiotics), chloramphenicol (phenicol antibiotics), chlorpropamide, glibenclamide, glipizide, tolbutamide (sulphonylurea hypoglycaemic antidiabetic agents), griseofulvine (antifungal agent), 5-nitroimidazole derivatives (metronidazole, ornidazole, secnidazole, tinidazole), ketoconazole, procarbazine (cytostatic agent).

+ **Central nervous system depressants**

4.6. Pregnancy and lactation

Not specified.

4.7. Effects on ability to drive and use machines

Impairment of vigilance, due to the presence of alcohol, can make driving of vehicles or the use of machines dangerous.

4.8. Undesirable effects

Risk of diarrhea at high doses.

4.9. Overdose

Not specified.

5) PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

CHOLERETIC-CHOLAGOGUE
(A: Digestive tract and metabolism)

5.2. Pharmacokinetic properties

Not specified.

5.3. Preclinical safety data

Not specified.

6) PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Alcohol, orange peel alcoholature, glycerol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

4 years.

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5. Nature and contents of container

120 ml in bottle (yellow glass type III).

6.6. Special precautions for disposal and other handling

No special requirements.

7) MARKETING AUTHORISATION HOLDER

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8) MARKETING AUTHORISATION NUMBER(S)

- 34009 302 279 8 5: 120 ml in bottle (yellow glass).

9) DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 08 August 1995
Last renewal: 08 August 2005.

10) DATE OF REVISION OF THE TEXT

November 1996.

11) DOSIMETRY

Not applicable.

12) INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Not subject to medical prescription.