SUMMARY OF PRODUCT CHARACTERISTICS

1) NAME OF THE MEDICINAL PRODUCT

CHOPHYTOL, coated tablet

2) QUALITATIVE AND QUANTITATIVE COMPOSITION

Artichoke (dry aqueous extract of leaves)..... 200.000 mg

For a coated tablet.

Each tablet contains 0.08 g of sucrose.

For a full list of excipients, see section 6.1.

3) PHARMACEUTICAL FORM

Coated tablet.

4) CLINICAL PARTICULARS

4.1. Therapeutic indications

Traditionally indicated to improve the renal and digestive elimination functions.

4.2. Posology and method of administration

Oral use. For adults only.

Absorb 1 to 2 tablets with water before the 3 main meals or when symptoms occur.

The duration of treatment is limited from 2 to 3 weeks.

4.3. Contraindications

Known hypersensitivity to one of the ingredients.

4.4. Special warnings and precautions for use

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

In case of diarrhea or abdominal pains, the treatment must be stopped.

This medicinal product contains sucrose. Patient with problems of fructose intolerance, glucose-galactose malabsorption syndrome or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains parahydroxybenozate and may cause allergic reactions (possibly delayed).

4.5. Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6. Pregnancy and lactation

No pertinent teratogenecity study in animal is available.
In clinical data, no malformative nor foetotoxical effect has been reported to date.
However, the following of exposed pregnancies is insufficient to exclude any risk.
Consequently, by safety reasons, it will be advisable not to use this medication during pregnancy.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

At high level intakes, risk of diarrhea.

Due to presence of parahydroxybenzoate (esters): urticaria

4.9. Overdose

Not applicable.

5) PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Not applicable.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Not applicable.

6) PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium trisilicate, pregelatinised maize starch, talc, magnesium stearate, gum lac, colophane, talc, gelatine, sucrose, calcium carbonate, colouring dispersion*, carnauba wax, polysorbate 80.

* Composition of the colouring dispersion: sucrose, yellow, black and brown iron oxide (E172), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214).

Each tablet contains 0.08 g of sucrose.

6.2. Incompatibilities

Not applicable.

6.3. Shelf-life

3 years.

6.4. Special precautions for storage

No special precautions of storage.

6.5. Nature and contents of container

Tube (polypropylene) closed by a stopper (polyethylene) of 60 or 180 coated tablets.
Box of 60 or 180 coated tablets in blisters PVC/Alu.
Box of 60 or 180 coated tablets in blisters PVC/PVDC/PE/Alu.

6.6. Special precautions for disposal and other handling

No special requirements.

7) MARKETING AUTHORISATION HOLDER

Laboratoires ROSA-PHYTOPHARMA
68, rue Jean-Jacques Rousseau
75001 PARIS
Standard: Tel.: +33 (0)1 34 80 55 80
Medical information: Tel.: +33 (0)1 34 80 72 60

8) MARKETING AUTHORISATION NUMBERS

- 34009 302 278 1 7: 60 coated tablets in tube (PP/PE)
- 34009 302 277 5 6: 180 coated tablets in tube (PP/PE)
- 34009 378 776 2 6: 60 coated tablets in blisters (PVC/Alu) 5 blisters of 12.
- 34009 382 948 9 7: 60 coated tablets in blisters (PVC/Alu) 2 blisters of 30.
- 34009 382 949 5 8: 180 coated tablets in blisters (PVC/Alu) 6 blisters of 30.
- 34009 399 039 7 2: 60 coated tablets in blisters (PVC/PVDC/PE/Alu) 2 blisters of 30.
- 34009 399 040 5 4: 180 coated tablets in blisters (PVC/PVDC/PE/Alu) 6 blisters of 30.

9) DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

First authorisation: 12 October 1995
Last renewal: 12 October 2010.

10) DATE OF REVISION OF THE TEXT

June 2013.

11) DOSIMETRY

Not applicable.

12) INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Not subject to medical prescription.