

SUMMARY OF PRODUCT CHARACTERISTICS

1) NAME OF THE MEDICINAL PRODUCT

CHOPHYTOL®

2) QUALITATIVE AND QUANTITATIVE COMPOSITION

Artichoke (dry aqueous extract of leaves) on maltodextrin_____200.000 mg

For a coated tablet.

Excipient with known effect: each tablet contains sucrose (0.08 g), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

For a full list of excipients, see section 6.1.

3) PHARMACEUTICAL FORM

Coated tablet.

Description

Round biconvex tablets with brown coating.

4) CLINICAL PARTICULARS***4.1. Therapeutic indications***

Traditionally indicated to improve the renal and digestive elimination functions:

- digestion recovery
- improvement in kidneys excretory function

4.2. Posology and method of administration

Oral use.

For adults only. 1–2 tablets three times a day with water before the meal or when symptoms occur. Treatment course duration is 2–3 weeks.

4.3. Contraindications

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- cholelithiasis
- severe hepatic failure
- acute diseases of liver, kidneys, bile duct and urinary tract
- patients with hereditary fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase deficiency
- children under age of 18
- pregnancy and lactation

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.

SmPC CHOPHYTOL, coated tablet

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 methyl parahydroxybenzoate and propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

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

No data present with regard to interaction with other medicinal products and other forms of interaction.

4.6. Fertility, pregnancy and lactation

No pertinent teratogenic study in animal is available.

In clinical data, no malformative nor foetotoxic 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

No effects.

4.8. Undesirable effects

Adverse events (AE) are classified by their rate as follows: very common $\geq 1/10$; common $\geq 1/100$ to $< 1/10$; uncommon $\geq 1/1,000$ to $< 1/100$; rare $\geq 1/10,000$ to $< 1/1,000$; very rare ($< 1/10,000$) and unknown (cannot be assessed based on the data available).

Unknown

- at high level intakes, risk of diarrhea.
- due to presence of parahydroxybenzoate (esters): urticaria

Reporting on adverse reactions

Post-marketing reports on the expected adverse reactions allow to continuously assess risk/benefit ratio of the medicines. Healthcare providers should report on any expected adverse reactions via the national reporting system: SCIENTIFIC CENTRE OF DRUG AND MEDICAL TECHNOLOGY EXPERTISE AFTER ACAD. E. GABRIELIAN» CJSC; Hot Line: (37410) 200505, (37496) 220505;

E-mail: vigilance@pharm.am; Web address: <http://www.pharm.am>

4.9. Overdose

Not applicable.

5) PHARMACOLOGICAL PROPERTIES

Pharmaco-therapeutic group: Alimentary tract and metabolism. Bile and liver therapy. Other drugs for bile therapy

ATC Code: absent

5.1. Pharmacodynamic properties

Antispasmodic, choleric, bile-enhancing, hepatoprotective and antioxidant effects are the pharmacodynamics properties shown in vitro and in vivo studies supporting the therapeutic indication of the drug CHOPHYTOL® solution. Phenolic constituents, particularly cynarin (one of the main biologically active chemicals), were demonstrated to be responsible of these properties.

5.2. Pharmacokinetic properties

The main compounds of artichoke [caffeoylquinic acids (cynarin), flavonoids (luteolin)] are rapidly absorbed, metabolized, and then excreted in the urine. Luteolin metabolites (i.e., sulfates or glucuronides) have also been detected in plasma and urine after leaf extracts administration.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, carcinogenic potential, toxicity to reproduction and development.

In vitro genotoxicity study performed on pure dry aqueous extract of artichoke leaves did not show any mutagenic potential of artichoke leaf extract.

Environmental Risk Assessment (ERA)

Due to its nature artichoke leaf extract is unlikely to result in a significant risk to the environment.

6) PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Magnesium trisilicate, pregelatinized 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), propyl parahydroxybenzoate (E216).

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

Store at a temperature below 25°C.

6.5. Nature and contents of container

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 MAYOLY SPINDLER

6 avenue de l'Europe

78400 Chatou - FRANCE

Standard: Tel.: 01 34 80 55 55

Medical information: Tel: +33 (0) 1 348072 60

SmPC CHOPHYTOL, coated tablet

8) MARKETING AUTHORISATION NUMBERS

- 378 776-2 or 34009 378 776 2 6: 60 coated tablets in blisters (PVC/Alu) 5 blisters of 12
- 382 948-9 or 34009 382 948 9 7: 60 coated tablets in blisters (PVC/Alu) 2 blisters of 30
- 382949-5 or 34009 382 949 5 8: 180 coated tablets in blisters (PVC/Alu) 6 blisters of 30
- 399 039-7 or 34009 399 039 7 2: 60 coated tablets in blisters (PVC/PVDC/PE/Alu) 2 blisters of 30
- 399040-5 or 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 authorization: 12 October 1995

Last renewal date: 12 October 2010.

10) DATE OF REVISION OF THE TEXT

April 2022.