

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) **(This information is intended for use by health professionals)**

1.NAME OF THE MEDICINAL PRODUCT: Conchevy

2.PHARMACEUTICAL FORM: Syrup

3.QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 ml of syrup contains:

Ivy leaf extract (Hedera helix) (dry extract) (10:1): 35 mg
standardized as Hedracosides (C) NLT 5%

Part used: Leaves

Solvent: Ethanol/Water

For a full list of excipients, see section 6.1

4.CLINICAL PARTICULARS

4.1-Therapeutic indications:

A traditional herbal medicinal product used as a treatment of productive cough & used as expectorant

4.2-Posology and method of administration:

Posology:-

- a- **Children from 2 to 5 years old :-** 2.5 ml one to two times/day
 - b- **Children from 6 to 11 years old:-** 5 ml one to two times/day
 - c- **12 years above / adult :-** 5 ml two to three times/day
- Or as directed by physician

Duration of use:- One week

- If symptoms persist, worsen or do not improve after use of Conchevy Syrup a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted
- **Method of administration:-** Orally, shake well before use

4.3-Contraindications:

- 1- Hypersensitivity to any ingredients or to plants of the Araliaceae family.
- 2- The use in children under 2 years age because of the risk of aggravation of respiratory symptoms.
- 3- Pregnancy & Lactation

4.4-Special warnings and precautions for use:

- Do not exceed stated dose
- If dyspnea, fever or purulent sputum occurs, a qualified health professional e.g. a doctor or a pharmacist should be consulted
- This product contain sucrose which may cause dental caries
- Caution is recommended in patients with gastritis or gastric ulcer.
- Keep out of reach of children
- To be used under medical supervision
- Patient with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose- isomaltose insufficiency should not take this medicine

4.5-Interaction with other medicinal products and other forms of interaction:

- No interaction studies have been performed
- Concomitant use with opiate antitussive such as codeine or dextromethorphan is not recommended or with medical advice.

4.6-Fertility, pregnancy and lactation:

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, Conchevy Syrup should not be used during pregnancy and lactation. Studies 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.

4.8-Undesirable effects:

- Gastrointestinal reactions (nausea, vomiting, diarrhea) have been reported. The frequency is not known.
- Allergic reactions (urticaria, skin rash, dyspnoea) have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 to: **Pharma Cure Pharmaceutical Industries**

Tel: 002-0133236852 / 002-01332253754 /002-0482657089 / 0002-01145004525.

Fax: 002-013-3236711 / 002-0482657088

E-mail: info@pharmacureonline.com

pv.center@eda.mohip.gov.eg

4.9-Overdose:

Overdose can provoke nausea, vomiting, diarrhea and agitation.

5-PHARMACOLOGICAL PROPERTIES:

A- Pharmacodynamic properties:

Not required.

B- Pharmacokinetic properties:

Not required.

C- Preclinical safety data:

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

6-PHARMACEUTICAL PARTICULARS:

6.1-List of excipients:

- Sucrose
- Citric acid monohydrate
- Carboxymethylcellulose sodium 2000
- Polysorbate 60
- Colloidal silicone dioxide (Aerosil 200)
- Orange liquid flavor
- Purified water add

6.2-Shelf life: 2 years

6.3-Storage conditions:

Keep at temperature not exceeding 30°C.

6.4-Nature & content of container:

Carton box containing one amber plastic bottle (PET) of 120 ml syrup , with HDPE plastic screw cap and LDPE internal foam liner + inner leaflet .

6.5-Special precautions for disposal and other handling:

This traditional herbal medicinal product does not require any special storage conditions.

7-Marketing authorisation holder & content:

- Pharma Cure Pharmaceutical Industries
- Address: Egypt , El Sadat city- 4th industrial zone – area 40.
- Fax : 002-0482657088
- E-Mail: Reg@PHARMACUREONLINE.COM

8- Marketing authorisation number(s):

9-Date of first authorisation:

10- Date of revision of the text: