Summary of Product Characteristics (SmPc)

(This information is intended for use by health professionals).

1.Name of the medicinal product : Monohexal
2.Pharmaceutical form: Syrup
3.Qualitative and quantitative composition:
Each 5 ml syrup contains:
Dried Ivy leaf powder extract of *Hedera helix* L. 45 mg
Contain NLT 3 % Hederacoside C
Part Used: Leaves
Extraction ratio: 4-12:1
Solvent used: Ethanol & water
4.Clinical particulars
4.1-**Therapeutic indications:**
Herbal medicinal product used as an expectorant in case of productive cough.
4.2-Posology, duration and method of administration:
A-Route of administration: Oral use
B-Recommended dose & Frequency:
Children from 2 to 5 years: 2.5 ml syrup twice daily or as directed by physician
Children from 6 to 12 years: 5 ml syrup twice daily or as directed by physician
Adolescents, adults and elderly: 5 ml syrup 3 times daily or as directed by physician
C-Duration of use:
If the symptoms persist longer than one week during the use of the medicinal product, a doctor or pharmacist should be consulted.

The bottle should be shaken before each use.

4.3-Contraindications:
Hypersensitivity to the active substance or to plants of the Araliaceae family or any of other inactive ingredients (listed section 6.1).
Children under 2 years of age because of the general risk of aggravation of respiratory symptoms through secretolytic drugs.
4.4-Special warnings and precautions for use:
Persistent or recurrent cough in children between 2- 4 years of age requires medical diagnosis before treatment.
When dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.
Caution is recommended in patients with gastritis or gastric ulcer.
-It has a laxative effect in overdose due to presence of sorbitol.
- Keep out of reach of children.

-To be used under medical Supervision

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

None reported

4.6-Fertility, pregnancy and lactation:

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No fertility data are 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:

-Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known.

-Allergic reactions (urticaria, skin rash, dyspnoea, anaphylactic reaction) have been reported. The frequency is not known.

-If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.

4.9-Overdose:

Overdose can provoke nausea, vomiting, diarrhoea and agitation.

5-PHARMACOLOGICAL PROPERTIES:

A- Pharmacodynamic properties

Pharmacotherapeutic group: respiratory system ,Proposed ATC code: R05 C

The mechanism of action is not known.

B- Pharmacokinetic properties

Not applicable

C-Preclinical safety data

Not applicable

6-PHARMACEUTICAL PARTICULARS:

6.1-List of excipients

Potassium sorbate, Citric acid anhydrous, Xanthan Gum, Sorbitol 70 % solution, Orange flavor, Purified water

6.2-Shelf life: Two Years

6.3-Storage conditions: - Store at a temperature not exceeding 30° c.

6.4-Nature & content of container: Carton box containing Amber PET bottle of 135 ml capacity filled with 120 ml of the product enclosed with white color HDPE screw cap with white color inner polyurethane liner with red tamper evident ring, with transparent graduated doser Polypropylene Plastic measuring cup & inner leaflet.

7-Marketing authorisation holder & contact:

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8- Marketing authorisation number(s):

9-Date of first authorisation

10- Date of revision of the text