1.6 Product Information

1.6.1 Summary of Product Characteristics

1.Name of the Medicinal Product:

Ivytus syrup 3. 5 mg/5 ml

2. Qualitative & Quantitative Composition:

Each 5 ml of the syrup contains dried Ivy leaf extract 0.035 g equivalent to 3.5 mg of Hederacoside C. for full list of excipients, see section 6.1'.

3. Pharmaceutical Form:

Syrup

4. Clinical Particulars:

4.1. Therapeutic indications:

Dried Ivy leaf is used for the treatment of inflammatory illnesses of the respiratory tract

4.2. Posology and method of administration:

Dosage:

For oral use only.

Shake the bottle well before use. Adults, the elderly, children aged 12 years and over: take 5 ml of oral liquid using the enclosed measuring cup 3 times daily.

The syrup should be taken in the morning, at midday and in the evening. Duration of use if symptoms worsen or persist after 7 days, a doctor or qualified healthcare pratitioner should be consulted. The product should not be used for more than 2 weeks. The use in children under 12 years of age is not recommended

4.3. Contraindications:

Ivy leaf is not recommended during pregnancy due to its emetine content; it may increase uterine contractions. Safety in pregnant or nursing women, young children or people with severe liver or kidney disease has not been established.

4.4. Special warning & precautions for use:

Warnings:

Ivy leaf is not recommended during pregnancy due to its emetine content; it may increase uterine contractions.

4.5. Interaction with other medicinal products & other forms of interaction:

Please tell your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, including medicines obtained without prescription. No interactions have become known so far. However, no studies have been carried out.

4.6. Pregnancy & lactation

Pregnancy

Ivytus Syrup should not be used during pregnancy and lactation without medical advice.

4.7. Effects on ability to drive & use machines:

No special Precautions are needed.

4.8. Undesirable effects:

Fairly extensive monitoring indicates that Ivy leaf rarely causes any noticeable side effects; however nausea and vomiting may occur with excessive doses, or in very susceptible people.

In rare cases, Ivytus Syrup may have a laxative effect due to the content of Sorbitol in the medicine.

In the event of shortness of breath, fever or purulent or bloody expectoration; the doctor should be consulted.

4.9. Overdose:

Overdosage can provoke nausea, vomitting, diarrhoea and excitation. In these cases, a physician should be consulted immediately.

5. Pharmacological Properties:

5.1. Pharmacodynamics:

Dried Ivy leaf liquefies mucus, relaxes convulsive cough and calms coughing. Troublesome and painful coughing is calmed but not blocked which is important for being able to cough up the mucus and thereby allow for trouble-free deep breathing.

Ivytus Syrup is free from alcohol, sugar and coloring; it has a pleasant honey flavor. Therefore it is suitable for children and at the same time it is effective for adults against bronchial illnesses.

5.2. Pharmacokinetics:

Hederacoside C (HDC) is one of the active ingredients in *Hedera helix* leaf extract (Ivy Ex.) and AG NPP709, a new botanical drug to treat acute respiratory infection and chronic inflammatory bronchitis. However, information regarding its pharmacokinetic properties remains limited.

5.3. Preclinical Safety Data:

Tests on carcinogenicity and reproductive toxicity have not been performed. Ivy leaf dry extract (DER 4-6:1), extraction solvent ethanol 30% (V/V) contained in the medicinal product showed no mutagenic potential in the Ames test.

6. Pharmaceutical Particulars:

6.1. List of excipients:

S. No.	Material	Function
EXCIPIENTS		
1.	Propylene Glycol Ph.Eur.	Vehicle
2.	Liquid Sorbitol (Non-crystallising) Ph.Eur.	Sweetening agent
3.	Citric Acid Monohydrate Ph.Eur.	Buffering agent
4.	Potassium Sorbate BP	Preservative
5.	Xanthan Gum BP	Suspending agent
6.	Honey Flavor	Flavoring agent
7.	Purified Water USP/BP	Aqueous Vehicle

6.2. Incompatibilities*:*

None known

6.3. Shelf life:

36 months

6.4. Special precautions for storage*:*

Store below 30^0C.

6.5. Nature & contents of container:

Amber glass bottle sealed with child-resistant cap (CRC) and placed in a printed carton along with a pack insert.

Pack size: 100 ml

6.6 Manufacturer:

Neopharma, Abu Dhabi, UAE

Plot No. A1 89-95,

Industrial City of Abu Dhabi (ICAD),

Mussafah, Abu Dhabi, UAE

6.7 Marketing Authorization Holder:

Neopharma, Abu Dhabi, UAE

Plot No. A1 89-95,

Industrial City of Abu Dhabi (ICAD),

Mussafah, Abu Dhabi, UAE