



**NESTHÄKCHEN®
EFEU SAFT**

Ivy Leaf Solution

**Ivy leaf
powdered extrakt**

*Anklam Extrakt article number:
00-115-0541-01P*


ANKLAMEXTRAKT

AGON
PHARMA · GMBH

QUALITY IS OUR PASSION

All from a single source

Anklam Extrakt combines high quality extracts with extraordinary service. We are particularly pleased to present our new exclusive service: **ready-to-sell products containing pharmaceutical extracts with stability data and complete documentation.**

We use only the best plant material for our extracts from selected suppliers of controlled and GACP compliant cultivation.

Ivy ... a leaf with healing properties

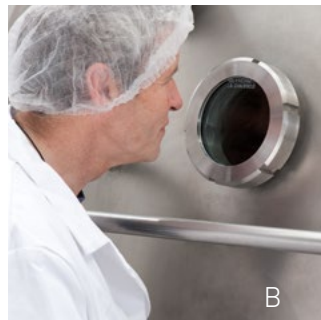
The protussive effect of ivy (i.e. cough-inducing and/or expectorant effect) has been clearly documented in numerous monographs. The removal of bronchial secretions from bronchia and trachea is facilitated and accelerated by taking ivy. Ivy is classified as expectorant.

// Images upper left to lower right
A. Ivy leaves
B. Qualified and motivated staff
with insight
C. Vacuum belt dryer in use
D. Percolator

Quality you can trust

The documentation of raw materials as well as the respective extracts is part of our service – for your product documentation as well as for your market approval documentation. Our specialised employees ensure that the quality of extracts meets the stringent control requirements according to GMP and HACCP standards.

Please do not hesitate to contact us for further information regarding our products and services. We will be pleased to help you.



Active pharmaceutical ingredient (API)

- Used plant material
Botanical name: *Hedera helix L.*
Used plant material: dried and cut leaves
Identity: complies with Ph. Eur. Monograph 2148
- Manufacturing data
Extraction solvent: Ethanol 30 % (w/w)
Drug Extract Ratio (DER) native : 4–8:1
Excipients: none
- Assay
Hederacoside C, calc. on the dried extract:
10 - 20 %

Ivy Leaf Solution

- 100 g Solution contains 0.545 g dry extract
- Pleasant taste (cherry flavor)
- Primary packaging in a glass bottle
- API and finished product are produced in Germany under pharmaceutical GMP conditions

Indication

Herbal medicinal product used as an expectorant in case of productive cough.

	dosage
Children (2-5 years)	2,5 ml, 2 times daily
Children (6-11 years)	5 ml, 2 times daily
Children 11 years and older and adults	5 ml, 3 times daily

Drug Registration Dossier

- ICH-conform. Stability data for API and finished product
- Manufacturing process validation for API and finished product
- Description of production process for API and finished product
- GACP compliant documentation of the herbal raw material

Regulatory status*: OTC - pharmacy only

Licensing Procedure

Well-Established Use bibliographic registration based on the HMPC monograph »*Hedera helix L.*, folium« dated November 24th, 2015.

Internationalisation

Depending on the conditions of the agreement, it is possible to use eCTD / English dossier in other countries.



Ivy leaf Monographs/Literature:

- Commission E
- ESCOP Monograph
- EMA Monograph (HMPC)
- European Pharmacopeia
- Pharmacopée Française
- Hagers Enzyklopädie

*Regulatory status in Germany

2 strong partners for YOUR success



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ANKLAM Extrakt

Pharmaceutical GMP manufacturer of herbal extracts for the global pharmaceutical industry with production site in Anklam, Germany.

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AGON Pharma

Approved pharmaceutical laboratory, regulatory affairs, specialised in the preparation of drug registration dossiers for herbal medicinal products.

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FROM GERMANY

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Disclaimer

The information that is provided regarding our ingredients is not applicable to nor intended to satisfy the requirements of all countries. Anklam Extrakt GmbH supplies ingredients as a raw material to companies that produce a variety of products containing our ingredients. Anklam Extrakt GmbH does not make any claims regarding the use of these finished products and each manufacturer is responsible for ensuring that the claims made for and use of its products comply with the regulatory requirement of the locations in which it is marketed. We accept no liability whatsoever for the content provided.

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