

# ASSESSMENT OF THE EFFICACY OF THE HEDUSSIN® MEDICINAL PRODUCT USE IN THE TREATMENT OF PRODUCTIVE (WET) COUGH

**First published:** 27/09/2017

**Last updated:** 31/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS21094

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### Study ID

22945

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### DARWIN EU® study

No

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### Study countries

 Poland

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### Study description

The staff that will take part in the study consists of paediatricians, general practitioners, internists, allergists, pulmonologists or doctors currently in the process of obtaining these specializations who lead the treatment of patients (in the form of outpatient healthcare) suffering from productive cough of various aetiologies in which, due to clinical indications, the HEDUSSIN® medicinal product has been introduced. Data on the efficacy of the treatment with the HEDUSSIN® medicinal product will be gathered in the Study Questionnaires (SQ) during two subsequent routine visits: first (1), where the Patient will be included in the Study, and second (2) approximately 7-10 days after the first one. The visits will be scheduled in accordance with the needs resulting from the Patient's clinical state. The inclusion of the Patient into the group where the given treatment method is used should not result from the Study Protocol. It should be dependent solely on the current medical practice and remain in accordance with the current medical knowledge. The medical history collection period, conducted by 50 investigators, is scheduled for 3 months.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Euopharma**

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**Institution**

# Contact details

## Study institution contact

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Study contact

[euopharma@euopharma.edu.pl](mailto:euopharma@euopharma.edu.pl)

## Primary lead investigator

Zbigniew Doniec

Primary lead investigator

# Study timelines

## Date when funding contract was signed

Planned: 02/11/2016

Actual: 02/11/2016

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## Study start date

Planned: 01/12/2016

Actual: 01/12/2016

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## Data analysis start date

Planned: 31/03/2017

Actual: 31/03/2017

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## Date of interim report, if expected

Planned: 31/05/2017

Actual: 31/05/2017

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## Date of final study report

Planned: 15/10/2017

Actual: 27/09/2017

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Phytopharm Kleka S.A.

## Study protocol

[PAES HEDUSSIN PB ENG.pdf](#) (249.38 KB)

## Regulatory

### Was the study required by a regulatory body?

No

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### Is the study required by a Risk Management Plan (RMP)?

Not applicable

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Disease epidemiology

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

Primary objective was efficacy of treatment with authorized medical product HEDUSSIN® in the therapy of productive cough in the course of respiratory tract infection in daily clinical practice (real life).

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Post Authorization Efficiency Study (PAES)

## Population studied

## **Short description of the study population**

Patient of either sex, aged 2 to 12 with diagnosis of a productive (wet) cough of various aetiology who were recommended to use HEDUSSIN® were included during 1st visit

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## **Age groups**

- Children (2 to < 12 years)
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## **Special population of interest**

Other

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## **Special population of interest, other**

Patients with productive (wet) cough

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## **Estimated number of subjects**

500

# Study design details

## **Outcomes**

Secondary objective was assessment of medical product HEDUSSIN® safety in the therapy of respiratory tract infection in daily clinical practice (real life).

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## **Data analysis plan**

The sample size of 500 Patients was based on the feasibility study. The analysis of the data obtained in the Study will be descriptive: the compiled data will consist of summarizing statistics such as quantities, average values, standard deviations, medians, minimal and maximal values of the observed frequencies/proportions. The effectiveness analysis will be conducted on the

basis of the population of Patients who will partake in all of the visits described in the Study Protocol.

## Documents

### Study results

[REPORT Hedussin FIN.pdf](#) (390.12 KB)

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## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### Data sources (types), other

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown