Drug Utilization Study for Pirinase Hayfever Relief for Adults 0.05% Nasal Spray (205708)

First published: 12/02/2016

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS12436

Study ID

25056

DARWIN EU® study

No

Study countries

United Kingdom

Study description

The Medicines and Healthcare products Regulatory Agency (MHRA) has required this study to evaluate consumer compliance with the product labelling of Pirinase Hayfever Relief for Adults 0.05% Nasal Spray over at least 2 allergy seasons. The purpose is to obtain real-world information on how consumers are complying with the product labelling This study will coincide with the launch of Pirinase Hayfever Relief for Adults 0.05% Nasal Spray in the United Kingdom (UK).The 5 primary objectives are:1. To assess if consumers of the correct age use the product: Ages 18 and older2. To assess the correct frequency of use: No more than 2 sprays in each nostril per day3. To assess reduction of dose: If symptoms improve, 1 spray in each nostril per day4. To assess if a physician is consulted before use: if a woman is pregnant or breastfeeding5. To assess if a physician is consulted: If symptoms have not improved after using for 7 days, a doctor is consultedThe 2 secondary objectives are:1. To assess if consumers do not use if they are taking medications for Human Immunodeficiency Virus (HIV)2. To assess if a physician is consulted: Not used more than 1 month continuously without consulting a doctor

Study status

Finalised

Research institutions and networks

Institutions

Concentrics Research

Contact details

Study institution contact

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor Cdr_mailbox@gsk.com

Study contact

Cdr_mailbox@gsk.com

Primary lead investigator

GSK Clinical Disclosure Advisor GSK Clinical Disclosure Advisor

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/02/2016

Actual: 29/01/2016

Study start date

Planned: 15/02/2016

Actual: 04/04/2016

Date of final study report

Planned: 30/09/2018

Actual: 19/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GlaxoSmithKline

Study protocol

gsk-205708-protocol-redact.pdf (1.37 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Not applicable

Main study objective:

The primary objective of this study is to evaluate if consumers comply with key warnings and directions on the outer label for selection and use of the drug.

Study drug and medical condition

Medicinal product name, other

Fluticasone propionate

Medical condition to be studied

Rhinitis allergic

Population studied

Short description of the study population

Approximately 1537 consumers in the UK who have purchased and used Pirinase Hayfever Relief for Adults 0.05% Nasal Spray for at least 7 days.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1.537

Study design details

Outcomes

To assess:- if consumers of the correct age use the product: (18 and older)- the correct frequency of use: No more than 2 sprays in each nostril/day- reduction of dose: If symptoms improve, 1 spray in each nostril/day- if a physician is consulted before use: if a woman is pregnant or breastfeeding- if a physician is consulted: If symptoms have not improved after using for 7 days, The two secondary objectives are the following:1. To assess if consumers do not use if they are taking medications for Human Immunodeficiency Virus (HIV)2. To assess if a physician is consulted: Not used more than 1 month continuously without consulting a doctor

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Data analysis plan

Primary endpoints will be analyzed individually and no adjustment for multiple comparisons will be performed. The compliance rate for each of the five primary endpoints will be reported and its two-sided 95% confidence limit will be computed using the exact method. The endpoint will have met the threshold for

success if the lower bound of the 2-sided 95% exact confidence interval (CI) is at least 80%. Secondary endpoints will be analyzed individually and no adjustment for multiple comparisons will be performed. The compliance rate for each of the secondary endpoints will be reported and its two-sided 95% confidence limit will be computed using the exact method. There are no success thresholds set for secondary endpoints.

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

Data sources (types), other

Information direct from consumers in the UK who have purchased and used the product

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown