Assessment of the effectiveness of additional Risk Minimisation Measures (aRMMs) among pharmacists for provision of Estradiol hemihydrate 10 micrograms vaginal tablets in a community pharmacy setting

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000274

Study ID

1000000274

DARWIN EU® study

No

Study countries

United Kingdom

Study description

To evaluate whether the additional risk minimisation measures (Pharmacy Guide, Pharmacy Checklist) are effective in enabling pharmacists to make appropriate decisions to supply Gina to consumers based upon pre-defined criteria.

Study status

Finalised

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Contact details

Study institution contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Actual: 22/02/2023

Study start date

Actual: 25/07/2023

Date of final study report

Actual: 31/01/2024

Study protocol

Gina NIS Protocol v6 eu-pas-reg Redacted.pdf (743.18 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Study design:

Cross sectional non-interventional web-based survey distributed across the UK to a representative mix of independent multiple ownership pharmacies to achieve a relevant sample size of pharmacists who have read the aRMM materials and conducted at least one consultation during the previous six months.

Main study objective:

The overall objective is to evaluate the effectiveness of the aRMMs in mitigating the risks of incorrect supply of Gina to patients in a community pharmacy. Specifically, the goals of the study are to:

• Demonstrate that the training provided by the company is effective in enabling pharmacists to make appropriate decisions to supply Gina based on contraindications and special warnings; this includes awareness and mitigation of safety concerns.

• Identify whether there are particular contraindications or warnings for which pharmacists consistently make the wrong supply decision.

• Establish ease of access to and ease of use of the aRMMs.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Web-based survey

Study drug and medical condition

Medicinal product name, other

Estradiol hemihydrate 10 micrograms vaginal tablets (Gina)

Study drug International non-proprietary name (INN) or common name

ESTRADIOL HEMIHYDRATE

Additional medical condition(s)

Vaginal atrophy

Population studied

Short description of the study population

Pharmacists

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)

- Elderly (≥ 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

Special population of interest, other

Pharmacists

Study design details

Setting

A structured, self-administered questionnaire comprised of closed questions comprising statements with multiple response choices (i.e. questions or statements asking the pharmacists to choose from a defined list of responses) will be used to collect the survey data. Questions will be asked in an order which provides a ‘funnel’ from general introductory topics towards the scenario-based questions, which constitute risk knowledge responses, on which KPIs have been set.

Outcomes

The questionnaire includes eight case study scenarios in the form of short representations of typical situations in which a patient requests Gina and is either supplied or not supplied, based on their presentation. In each case, the option to “supply” or “do not supply” will be chosen by the respondents and will be correct or incorrect. The number of correct responses to each scenario will assess the knowledge of the pharmacists.

Data analysis plan

The knowledge level analysed using descriptive statistics and confidence intervals will be used to determine the effectiveness of the aRMMs.

Documents

Study results

Gina NIS Report eu-pas-reg Redacted.pdf (4.55 MB)

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.

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

No