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

First published: 29/07/2024 Last updated: 29/07/2024





## Administrative details

#### **EU PAS number**

EUPAS1000000274

#### Study ID

1000000274

#### **DARWIN EU® study**

No

#### **Study countries**

### **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**

First published: 01/02/2024

**Last updated:** 01/02/2024

Institution

## Contact details

### Study institution contact

Clinical Transparency (dept. 2834) Novo Nordisk A/S pactadmin@novonordisk.com

Study contact

#### pactadmin@novonordisk.com

### **Primary lead investigator**

Clinical Transparency (dept. 2834) Novo Nordisk A/S

**Primary lead investigator** 

# 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

#### Name of medicine, 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