# Assessment of safety of Diphereline® SR 11.25 mg in Polish patients with prostate cancer (A-38-52014-163)

First published: 12/11/2014

**Last updated:** 01/03/2024





# Administrative details

<b>EU PAS number</b> EUPAS7938		
Study ID		
30162		
DARWIN EU® study		
No		
Study countries Poland		

**Study description** 

This national, post marketing multicentre, observational, non-controlled study designed to formally assess the safety of Diphereline® SR during 12-month observation in patients with locally advance or invasive prostate cancer in normal clinical practice. Only patients who started therapy with Diphereline® SRwere considered as the study participants. The study documents (CRF) recorded justification for the prescription of Diphereline® SR, clinical stage (TMN classification) and grade (Gleason score) of prostate cancer, concomitant diseases and medication. The main outcome is the assessment of adverse (AE) or Serious Adverse Event (SAE) and Adverse Drug Reaction (ADR) related to the use of Diphereline® SR recorded during every 3-months visits necessary for Diphereline® SR injection.

#### **Study status**

Finalised

## Research institutions and networks

## Institutions

## **Ipsen Pharma**

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 210 centres are involved in the study

## Contact details

#### **Study institution contact**

Medical Director, Uro-Oncology clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

## **Primary lead investigator**

Medical Director, Uro-Oncology

**Primary lead investigator** 

# Study timelines

#### Date when funding contract was signed

Planned: 01/08/2008

Actual: 01/08/2008

#### Study start date

Planned: 31/08/2008

Actual: 31/10/2008

## Date of final study report

Planned: 30/09/2010

Actual: 30/09/2010

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Ipsen

# Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

# Methodological aspects

# Study type

# Study type list

### **Study topic:**

Disease /health condition

Human medicinal product

#### Study type:

Non-interventional study

#### Scope of the study:

Safety study (incl. comparative)

#### **Data collection methods:**

Primary data collection

#### Main study objective:

Primary objective: monitoring of the safety of Diphereline® SR 11.25 mg in general practice. Secondary objective: safety in locally advanced and metastatic prostate cancer.

# Study Design

#### Non-interventional study design

Other

#### Non-interventional study design, other

Post-marketing Observational Study

# Study drug and medical condition

#### **Anatomical Therapeutic Chemical (ATC) code**

(L02AE04) triptorelin

triptorelin

#### Medical condition to be studied

Prostate cancer

# Population studied

#### Short description of the study population

Patients with locally advance or invasive prostate cancer in normal clinical practice. Only patients who started therapy with Diphereline® SR were considered as the study participants.

#### Age groups

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

Other

#### Special population of interest, other

Prostate cancer patients

#### **Estimated number of subjects**

3000

# Study design details

#### Outcomes

The assessment of adverse (AE) or Serious Adverse Event (SAE) and Adverse Drug Reaction (ADR) related to the use of Diphereline® SR recorded during every 3-months visits necessary for Diphereline® SR injection.

#### Data analysis plan

Statistical analyses were performed with the use of STATISTICA 8.0 PL software. Distribution of quantitative variables were shown by mean values and standard deviations, and of qualitative variables by absolute and relative frequencies. Medical Dictionary for Regulatory Activities (MedDRA, version not specified) dictionary was used to code separately AE and SAE. The frequency of AE and ADR was calculated for the population exposed for at least one dose of Diphereline ® SR 11.25 mg.

## 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

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

## CDM mapping

# Data quality specifications

#### **Check conformance**

Unknown

## **Check completeness**

Unknown

## **Check stability**

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No