Ozurdex® (dexamethasone) Implant Risk Management Plan Injector's Guide Assessment Australia

First published: 04/06/2018

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS23093

Study ID

24504

DARWIN EU® study

No

Study countries

Australia

Study description

This annex is provided in order to present a comprehensive assessment of the risk and benefits of OZURDEX® (dexamethasone) 700 µg intravitreal implant and to add Australia-specific risk assessment information to the risk management plan (RMP) v8.1

Study status

Finalised

Research institutions and networks

Institutions

So What Research Pty Ltd

Contact details

Study institution contact

George Labib CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

George Labib

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 29/04/2016

Study start date
Actual: 20/12/2017

Date of interim report, if expected
Actual: 21/12/2017

Date of final study report
Actual: 29/01/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

OZURDEX_AUSTRALIA_RMP_ASA_v5.3_RVO-DME-Uveitis_May2017_Redacted.pdf
(1.22 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

the goal of the survey is to evaluate physicians' comprehension of the key risks related to OZURDEX® injection described in the educational materials.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Online survey

Study drug and medical condition

Medicinal product name

OZURDEX

Population studied

Short description of the study population

Australian Retinal Specialists/Ophthalmologists between 24 November 2017 and 20 December 2017.

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)

Estimated number of subjects

20

Study design details

Outcomes

To evaluate the effectiveness of the education materials and their effectiveness as a measure to reduce all the specified important identified risks.

Data analysis plan

The pass rate as defined in the survey for each individual HCP is a result of at least 80% correct. Therefore, a HCP is defined as passing with 19/23 (approx. 80%) for more correctly answered questions

Documents

Study results

Ozurdex RMP REPORT FINAL_29Jan18_clean_v3.0_Redacted.pdf (464.61 KB)

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

Physician survey

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