Monitoring of Compliance with Exenatide Prescribing Guidelines in Canada: Drug Utilisation Study of BYETTA in Canada for 2011-2014

First published: 09/03/2017

Last updated: 30/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS17963

Study ID

19058

DARWIN EU® study

No

Study countries

Canada

Study description

This was a retrospective cohort study conducted to evaluate adherence to the labelling recommendations for BYETTA use in Canada. Data from the Canadian IMS Brogan's Longitudinal Patient Data assets (LRx) for 2011-2014 was used.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Sarah Frise

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 20/01/2011

Actual: 20/01/2011

Study start date
Planned: 01/06/2011

Actual: 01/06/2011

Data analysis start date
Planned: 01/07/2014

Actual: 01/07/2014

Date of final study report
Planned: 25/03/2015

Actual: 25/03/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca Canada

Study protocol

D5550N00008_Protocol.pdf (825.15 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

D5550N00008

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To evaluate BYETTA use outside labelling indications in Canada.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective database study

Population studied

Short description of the study population

All patients in the IMS Brogan’s LRx database who have been prescribed Byetta in Canada during the analysis period from 2011-2014.

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

1027

Study design details

Outcomes

The majority of patients were treated with BYETTA in accordance with the Canadian Product Monograph. One-third of patients in the inferred on-label category displayed some off-label behaviour at certain time points, mainly in conjunction with basal insulin

Data analysis plan

This was a retrospective cohort study, with no hypothesis test. Number and proportion of patients were classified in each patient cohort of “inferred on-label”, “off-label” and “inferred off-label”, data were described by study year and gender. Overall off-label use was calculated. Concomitant use of BYETTA with insulin or TZD was further studied. Data on age and gender were obtained based on records documented in the prescription database when a patient initiating a treatment with BYETTA. The patterns and drug classes of concomitant medications were studied and described for each of the three patient cohorts.

Documents

Study results

D5550N00008_CSR_Redacted.pdf (1.67 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.

Data sources

Data source(s), other

Longitudinal Prescription Data - Canada

Data sources (types)

Other

Data sources (types), other

Prescription event monitoring

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