A drug utilisation study to assess the effectiveness of risk minimisation measures and describe the prescribing practices of Doreta SR and tramadol/paracetamol combinations in Europe (DUS Doreta SR and tramadol/paracetamol combination)

First published: 06/07/2022

Last updated: 30/01/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47962

EU PAS number

EUPAS47961

Study ID

47962

DARWIN EU® study

No

Study countries

- ☐ Czechia
- ☐ Hungary
- ☐ Poland

Study description

A drug utilisation study to assess the effectiveness of risk minimisation measures and describe the prescribing practices of Doreta SR and tramadol/paracetamol combinations in European countries

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

☐ United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

Dorothea von Bredow

Study contact

Dorothea.vonbredow@iqvia.com

Primary lead investigator

Dorothea von Bredow

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/01/2021

Actual: 26/01/2021

Study start date

Planned: 01/12/2022

Actual: 17/01/2022

Data analysis start date

Planned: 03/04/2023

Actual: 21/06/2023

Date of final study report

Planned: 30/06/2023

Actual: 25/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

KRKA, d. d., Novo mesto

Study protocol

KrKa Doreta SR DUS PASS protocol V3.0_17 January 2022.pdf(2.5 MB)

2673514_ Krka Doreta SR DUS PASS protocol_V4_23 Feb-2023.pdf(755.4 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)

Other study registration identification numbers and links

HU/H/0190/003/II/035

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

This is a cross-sectional pre-post, drug utilisation study conducted using secondary data in outpatient settings. It consists of 2 distinct study periods: pre-RMM period and post-RMM period.

Main study objective:

This study aims to describe the prescribing practices before and after the implementation of RMMs for Doreta SR proposed by the MAH (i.e. changes in the product information, changes in the product packaging and dissemination of Direct Healthcare Professional Communication DHPC).

Study drug and medical condition

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

PARACETAMOL

TRAMADOL

Anatomical Therapeutic Chemical (ATC) code

(N02AJ13) tramadol and paracetamol

tramadol and paracetamol

Population studied

Short description of the study population

Any dispensed prescriptions of oral FDCs of tramadol and paracetamol during the study periods

---

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

100000

Study design details

Setting

Electronic dispensed pharmacy data/claims data from three European countries: the Czech Republic, Hungary, and Poland.
Prescribing practices between Pre-RMM period and post RMM period were compared

---

Outcomes

To describe the use of Doreta SR and immediate-release FDCs of tramadol/paracetamol pre- and post-RMM implementation in terms of: Total dose dispensed Indication of the dispensed prescriptions Total dose dispensed per indications Duration of dispensed prescriptions per treatment Comorbidities Concomitant dispensed prescriptions, To describe the demographic characteristics of patients prescribed with Doreta SR and immediate-release FDCs of tramadol/paracetamol pre- and post-RMM. To describe the characteristics of prescribers of Doreta SR and immediate-release FDCs of tramadol/paracetamol pre- and post-RMM

Data analysis plan

Descriptive analysis

Summary results

This report provides insights into the prescribing patterns of Doreta SR and IR FDCs of tramadol/paracetamol in the pre-RMM and post-RMM periods in the Czech Republic, Poland, and Hungary. Generally, both drugs were dispensed in increased doses and for a more extensive duration in the post-RMM period. It is possible that prescribers intended to provide significant medication refills to patients due to the COVID-19 pandemic. In Hungary, dorsalgia was the most prevalent indication for dispensed prescriptions. For both periods, opioids were predominantly dispensed with Doreta SR and IR FDCs of tramadol and paracetamol. No prescriptions in the Czech Republic and Poland as well as zero

to nine prescriptions in Hungary for monoamine oxidase inhibitors, which must not be taken together with FDC of tramadol/paracetamol, were dispensed in both periods. As evidenced by sex- and age-related patterns in the use of analgesics, Doreta SR and IR FDC of tramadol/paracetamol were most commonly prescribed to elderly individuals and women in both periods. Both drugs were primarily prescribed by general practitioners.

Documents

Study report

2673514__Krka_Doreta_SR_DUS_KKLR402019_Final_Report_V2.0_25012024.pdf (1.39 MB)

Data management

Data sources

Data source(s), other

IQVIA LifeLink Poland, NHIF Claims database Hungary, IQVIA Diagnoses Insight database Czechia

---

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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