

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

### EU PAS number

EUPAS47961

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### Study ID

47962

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### DARWIN EU® study

No

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### Study countries

 Czechia

 Hungary

 Poland

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## 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

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## 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

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**Study contact**

[Dorothea.vonbredow@iqvia.com](mailto: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

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**Study start date**

Planned: 01/12/2022

Actual: 17/01/2022

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**Data analysis start date**

Planned: 03/04/2023

Actual: 21/06/2023

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**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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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## **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

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### **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)
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### **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

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## **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

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## **Data analysis plan**

Descriptive analysis

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## **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

### 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

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

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### Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown