Safety Profile of Extended Release (650 mg) Acetaminophen Products in the United States: Non-Interventional Post-authorization Safety Study of the National Poison Data System and Food and Drug Administration Adverse Event Reporting System Databases

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Study Finalised

Administrative details

EU PAS number

EUPAS23109

Study ID

35646

DARWIN EU® study

No

Study countries

United States

Study description

The research question addressed by this study is: what is the safetyprofile of extended release acetaminophen use among adolescents andadults (aged ≥12 years) in the United States (US)? This study aims todescribe the safety profile of extended release acetaminophen in the USthrough evaluation of two independent surveillance data systems, theNational Poison Data System (NPDS) and Food and DrugAdministration (FDA) Adverse Event Reporting System (FAERS).Specifically, the study aims to characterize adolescent and adult (aged ≥12 years) exposures to extended release acetaminophen products, describe and compare reporting rates for extended and immediate release acetaminophen products, compare outcomes of extended and immediate release acetaminophen product exposures among US adolescents and adults (age ≥12 years).

Study status

Finalised

Research institutions and networks

Institutions

Rocky Mountain Poison & Drug Safety (RMPDS)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Richard Dart

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/02/2018

Actual: 20/02/2018

Study start date

Planned: 18/01/2018

Actual: 20/02/2018

Data analysis start date

Planned: 18/01/2018

Actual: 20/02/2018

Date of final study report

Planned: 08/05/2020

Actual: 01/05/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Johnson and Jonson Consumer Inc.

Study protocol

NI-PASS Protocol APAP ER 2018-03-27 CONNECT.pdf (260.58 KB)

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The objective of this study is to describe the safety profile of extended release acetaminophen in the US through evaluation of two independent surveillance data systems, the National Poison Data System (NPDS) and the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, observational (non-interventional), Post-authorization Safety Study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N02BE01) paracetamol

paracetamol

Population studied

Short description of the study population

NPDS data are from adolescent and adult (age ≥12 years) patients exposed to extended release (650 mg) or immediate release (325 or 500 mg) acetaminophen products reported to a poison center between 2007 and 2016. FAERS data include US reports of adolescent and adult (age ≥12 years) patients with a primary suspect, secondary suspect, concomitant, or interacting drug of extended release (650 mg) or immediate release (325 or 500 mg) acetaminophen products reported to the FDA between 2011 and 2016.

The NPDS patient selection criteria are:

1. an adolescent or adult patient aged ≥12 years
2. exposure occurred in the US
3. exposure to extended release (650 mg solid acetaminophen) or immediate release acetaminophen (325 mg or 500 mg acetaminophen) product

The FAERS patient selection criteria are

1. an adolescent or adult aged ≥12 years
2. exposure occurred in the US (where reported, US reporter and event occurred location; non-foreign report)
3. primary suspect drug, secondary suspect drug, concomitant drug, or interacting drug name is extended release or immediate release acetaminophen product

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Age groups

- 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

35.000

Study design details

Data analysis plan

Using data from both databases, descriptive statistics will be used to characterize exposures and outcomes for extended release acetaminophen product exposures. Rates will be calculated with exact 95% Poisson confidence intervals. Rates and outcome distributions will be compared for extended release and immediate release acetaminophen product exposures.

Documents

Study results

APAP PASS CSR 01MAY2020 Approved Compressed.pdf (4.39 MB)

Extended Release Acetaminophen COMBINED Report FINAL 01May2020.pdf (7.04 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 sources (types)

Other

Data sources (types), other

Self-reported poison center 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

No