

# Retinoid-containing medicinal products and Neuropsychiatric disorders: A descriptive analysis of EudraVigilance data

**First published:** 20/01/2021

**Last updated:** 02/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS36901

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### Study ID

36902


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### DARWIN EU® study

No

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### Study countries

 United Kingdom

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### Study description

A cross-sectional descriptive study of case reports of Neuropsychiatric disorders to Retinoid-containing medicinal products was conducted. Case reports were extracted from EudraVigilance, from inception to 19 July 2016 where single or multi-ingredient formulations of Acitretin, Adapalene, Alitretinoin, Bexarotene, Isotretinoin, Tretinoin, Tazarotene were reported as suspect or interacting medicinal products and there was at least one Preferred Term of the Psychiatric disorders SOC.

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## Study status

Finalised

## Research institutions and networks

### Institutions

#### European Medicines Agency (EMA)

**First published:** 01/02/2024

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Institution

## Contact details

### Study institution contact

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Study contact

[luis.pinheiro@ema.europa.eu](mailto:luis.pinheiro@ema.europa.eu)

## Primary lead investigator

Pinheiro Luis

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 06/09/2016

Actual: 06/09/2016

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### Study start date

Planned: 06/09/2016

Actual: 06/09/2016

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### Data analysis start date

Planned: 31/08/2016

Actual: 31/08/2016

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### Date of interim report, if expected

Planned: 21/09/2016

Actual: 21/09/2016

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### Date of final study report

Planned: 23/09/2016

Actual: 27/09/2016

## Sources of funding

- EMA

# Study protocol

[Retinoids Art 31 Data Analysis synopsis - 20160905.pdf](#) (109.66 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)?**

Not applicable

## Other study registration identification numbers and links

EMA/H/A-31/1446

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Other

**If 'other', further details on the scope of the study**

Description of case series

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To provide a comprehensive overview of the case reports of neuropsychiatric adverse events associated with the use of retinoid-containing medicinal products.

## Study Design

**Non-interventional study design**

Cross-sectional

Other

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**Non-interventional study design, other**

Case-series

## Study drug and medical condition

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

ACITRETIN  
ADAPALENE  
ALITRETINOIN  
BEXAROTENE  
ISOTRETINOIN  
TRETINOIN  
TAZAROTENE

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### **Medical condition to be studied**

Depression  
Suicidal ideation  
Anxiety

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### **Additional medical condition(s)**

Psychiatric disorders System Organ Class

## Population studied

### **Short description of the study population**

All case of neuropsychiatric disorders reported to any retinoidcontaining medicinal product from inception up to July 2016.

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### **Age groups**

- 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**

10295

## Study design details

### **Data analysis plan**

Summary tabulations were produced for the distribution of reports per retinoid, route of administration, reporting year (receive date), location (country), demographic characteristics (age groups, gender), medical history (history of psychiatric disorders) and duration of treatment. Where possible, correlations of the abovementioned variables were provided. To report on relevant MedDRA PTs, Proportional reporting ratios were used as a disproportionality metric and were calculated for each INN and MedDRA PT. This data was analysed cumulatively for all retinoids, stratified by individual retinoid and stratified by route of administration. Output tables were adjusted accordingly. The analysis pertaining to fatal cases resulting from self-injury was presented separately as a subgroup analysis.

## Documents

### **Study results**

[Retinoid Art 31 referral - EV analysis of neuropsychiatric reactions.pdf](#) (592.05 KB)

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## 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

EudraVigilance

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### Data sources (types)

[Spontaneous reports of suspected adverse drug reactions](#)

## 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**

No