# Pregnancy Prevention Program Section of the Risk Management Plan for Soriatane® (acitretin): Survey to Assess Physician and Pharmacist Understanding of the Risk of Teratogenicity Associated with Soriatane

**First published:** 14/11/2017

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS21151

**Study ID**

23298

**DARWIN EU® study**

No

**Study countries**

☐ Canada

**Study description**

This is a one-time survey study of Canadian physicians and pharmacists. Two separate survey questionnaires will be developed for physicians and pharmacists, respectively. 1. The Pretest Phase Survey pretesting is used to evaluate the readability and interpretation of each survey comprehension question. This involves pretesting and functionality testing of the internet-hosted survey tool, including the electronic data-capture system. In addition, the pretesting is performed to determine if any question performance problems are related to clarity of wording versus respondent understanding. 2. The Full Launch Phase The study procedure will consist of recruiting prescribers and dispensers of Soriatane in Canada to participate in a voluntary online survey. The expected duration of the survey fielding will be 8-12 weeks.

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**Study status**

Finalised

# Research institutions and networks

## Institutions

### Analysis Group Inc

# Contact details

**Study institution contact**

Mei Sheng Duh CT.Disclosures@abbvie.com

**Study contact**

CT.Disclosures@abbvie.com

**Primary lead investigator**

Bai Yan

**Primary lead investigator**

## Study timelines

**Date when funding contract was signed**

Planned: 15/09/2017

Actual: 25/07/2017

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**Study start date**

Planned: 15/09/2017

Actual: 25/07/2017

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**Date of final study report**

Planned: 29/12/2017

Actual: 21/03/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Allergan/Arelaz

## Study protocol

Soriatane_Health_Canada_Survey_Protocol_18Aug2017_AGN Signed.pdf(9.06 MB)

## 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

CMO-EPI-DERM-0527

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Other

**If ‘other’, further details on the scope of the study**

Survey

**Data collection methods:**

Primary data collection

**Main study objective:**

To understand: •How physicians prescribe Soriatane •What teratogenicity risks physicians & pharmacists are aware of & communicate to women of childbearing potential •What strategies they use to minimize the likelihood of pregnancy among women of childbearing potential •Their awareness & use of existing educational materials regarding appropriate prescription & dispensing of Soriatane

## Study Design

**Non-interventional study design**

Cross-sectional

## Population studied

**Short description of the study population**

Canadian physicians and pharmacists who are prescribers and dispensers of Soriatane.

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**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)

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**Special population of interest**

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

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**Estimated number of subjects**

420

# Study design details

**Data analysis plan**

Responses for all questions of each survey will be tabulated and reported descriptively, including frequencies with percentages for categorical variables as appropriate. All results will be reported in the aggregate for each survey sample.

# Documents

**Study results**

Soriatane Survey Assessment Report_FINAL_02.15.2018_EU PAS.pdf(793.04 KB)

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

This is a one-time survey study of Canadian physicians and pharmacists. Two separate survey questionnaires will be developed for physicians and pharmacists.

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

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**Check logical consistency**

Unknown

# Data characterisation

**Data characterisation conducted**

Unknown