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

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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.

Study status

Finalised

Research institutions and networks

Institutions

Analysis Group Inc

Contact details

Study institution contact

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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

Study start date

Planned: 15/09/2017

Actual: 25/07/2017

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.

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)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

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

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

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

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown