
1. ABSTRACT

Title

Effectiveness of the Nplate® additional risk minimisation materials implemented in Australia.

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Keywords

Romiplostim, risk management, risk minimisation effectiveness

Rationale and Background

Medication errors have been designated as an important identified risk for Nplate in the Nplate European (EU) Risk Management Plan (RMP) and the Australia Specific Annex (ASA). To mitigate the risk of medication errors associated with Nplate, additional risk minimisation materials (aRMMs) are provided by Amgen Australia to healthcare professionals (HCPs) prescribing, preparing and administering Nplate and also to patients who are self-administering Nplate.

This study was conducted to measure the effectiveness of the aRMMs in mitigating medication errors occurring with the administration of Nplate.

Research Question and Objectives

The objectives of this study were to assess:

- HCP awareness, usage and utility of the aRMMs
- HCP assessment of competency of patients for self-administration
- Which elements of the aRMMs are considered by HCPs as the most useful
- The proportion of adult patient population who self-administer Nplate
- Whether there has been a change in the incidence of medication error reports

Study Design

This study involved an online questionnaire targeting haematologists and haematology nurses involved in treating patients with Nplate. The online survey was conducted by a third party vendor, under Australian Market Research guidelines.

This study also involved an assessment of Nplate medication error reports received by Amgen Australia and captured in the Amgen Global Safety Database (Argus).

Setting

The on-line questionnaire targeted haematologists and haematology nurses across Australian healthcare settings who have treated patients with Nplate.

The assessment of medication error reports received in Australia was completed on data pulled from the Amgen Global Safety Database during the period 12 December 2018 to 31 December 2021, inclusive.

Subjects and Study Size, Including Dropouts

Haematologists and haematology nurses were eligible to complete the online survey providing they had treated patients with immune thrombocytopenia (ITP) with Nplate within the last 12 months.

Twenty one haematologists and nine haematology nurses completed the survey.

Data Source(s) and Methods

This study utilised data obtained from survey responses from healthcare professionals (haematologists and haematology nurses) and from data extracted from the Amgen Drug Safety Database.

Data from haematologists and haematology nurses was collected by an online questionnaire conducted by third party vendor under Market Research governance.

Data from the Amgen Drug Safety Database was retrieved utilising standard Medical Dictionary for Regulatory Activities (MedDRA) search strategy for medication errors (SMQ). The broad search strategy was used. The Medication Error SMQ list of terms are included in [Annex 1](#).

Results

Awareness and usage of the aRMMS is lower in haematologists compared with haematology nurses.

The materials were considered effective by those respondents who were aware of the materials.

Assessment of medication errors indicated that no serious medication errors have occurred and only one medication error occurred in the self-administration setting.

Discussion

The materials are considered by both haematologists and haematology nurses to have a positive impact, however awareness and usage of the materials is lower in haematologists compared with haematology nurses.

Evaluation of the Nplate medication error reports in Australia indicate that there were non-serious medication errors reported, and only one report involving self-administration, indicating that the materials available to support self-administration and dose calculation are effective.

The materials are considered effective, however awareness of the materials could be improved.

Marketing Authorization Holder(s)

Amgen Australia Pty Ltd.

Names and Affiliations of Principal Investigators

Not applicable. Survey respondents were anonymous.