HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Product Information for Medicines

The HPRA would like to remind healthcare professionals of the importance of regular review and monitoring of product information for medicines, to support awareness of relevant updates/changes which may affect prescribing, dispensing, administration or monitoring practices. Following the assessment of new safety data, product information is regularly updated, with several hundred recommendations to update product information made at EU level annually. It is also important that patients and care-givers, as appropriate, are made aware of the information contained in the Package Leaflet (PL) and should be encouraged to read it prior to and indeed during their treatment and to discuss any relevant concerns with a healthcare professional involved in their care.

The product information is comprised of the Summary of Product Characteristics (SmPC) for healthcare professionals and the PL for patients. These documents are issued when a medicine is first licensed for use and are reviewed and updated as necessary throughout the lifetime of a medicine, to reflect the current state of knowledge of the medicine and the risks associated with its use.

SmPCs and PLs for medicines currently authorised in Ireland are accessible via the HPRA website (www.hpra.ie) via the 'Find a Medicine' search function. It is important to note that the product information for medicines authorised via the centralised application procedure (CAP), is available on the European Medicines Agency (EMA) website. The HPRA website provides a link to the EMA website via the SmPC or PL link under the relevant medicine. Once on the EMA website (www.ema.europa.eu), search the medicine name using the search box available, click on the relevant product and the product information is accessible from the 'Table of Contents'.

The SmPC provides the basis of information for healthcare professionals to use a medicine safely, effectively and in the most appropriate manner. It is also a legal document, agreed between the HPRA/EMA and the relevant pharmaceutical company. The format and content of the SmPC is laid down in EU/national legislation and regulatory guidance documents. Use of a medicine outside the conditions/recommendations described in the SmPC falls under the responsibility of the healthcare professional. It is important to note that the SmPC is not intended to provide general advice on the treatment of particular medical conditions, however, specific aspects of the treatment related to use of the medicine, or its effects may be mentioned. Similarly, general advice on administration procedures is not included, but any advice specific to the medicine concerned, such as specific information on reconstitution will be included, if appropriate.

The PL reflects the more comprehensive information described in the SmPC but is presented in an abbreviated and easy-to-read format for patients. The PL is drawn up in accordance with the SmPC and is subject to user-testing to ensure its ease of readability by patients/consumers. It plays an essential part in supporting the safe and effective use of a medicine by a patient. Consequently, it is important that a PL is provided each time a product is dispensed.

In specific situations where there is a need, for safety reasons, to take immediate action or change current practice in relation to a medicinal product, a direct healthcare professional communication (DHPC) is disseminated, prior to the

product information change. Situations when a DHPC may be disseminated include, for example, new major warnings or precautions for use in the product information, new data identifying a previously unknown risk or a change in the frequency/severity of a known risk, new recommendations for preventing or treating adverse reactions. A DHPC may also be used to inform of a suspension/withdrawal/revocation of a marketing authorisation for safety reasons. A DHPC is delivered directly to individual healthcare professionals by a marketing authorisation holder (MAH) by post, following approval by the HPRA. A DHPC is identified as important new safety information by the following identifier that appears at the top of a HPRA-approved DHPC:

DHPCs are also published on the HPRA website under 'Latest updates' 'Safety notices' on the homepage. In each edition of the HPRA Drug Safety Newsletter, a list with links to DHPCs published in the interval is provided.

Key Messages

- The current versions of the product information should be consulted regularly to ensure medicines are used in the safest and most effective manner.
- Product information (SmPC and PL) is available for medicines currently authorised in Ireland from the HPRA/EMA websites (accessible from www.hpra.ie and www.ema.europa.eu).
- Patients should be encouraged to read the PLs provided with their medicines and to discuss any concerns with a relevant healthcare professional.
- Direct healthcare professional communications are circulated by the marketing authorisation holder to communicate important safety information to HCPs and are also available on the HPRA website.

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