



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

Veronica Alexander
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Medicines and Healthcare Products Regulatory Agency
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Dear Ms. Alexander,

Re: Arm 66 – Extended Maximum Treatment Period and Pack Size Changes to a Pharmacy Medicine

We write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation document.

The Royal Pharmaceutical Society of Great Britain is the current professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy whilst, it also promotes the profession's policies and views to a range of external stakeholders in a number of different forums. Following the publication in 2007 of the Government White Paper Trust, Assurance and Safety - The Regulation of Health Professionals in the 21st Century, the Society is working towards the demerger of its regulatory and professional roles. This will see the establishment of a new General Pharmaceutical Council and a new Professional body in 2010.

The Society supports the extended maximum treatment period and pack size changes to the pharmacy medicine, Voltarol Emulgel P, however we request that the following points are taken into consideration:

Reclassification Summary

Section 2. Product Details - Pack Size.

With reference to Section 5.the Society agrees and encourages the use of clear instructions on the product package of the new dispenser pack to discourage product overuse.

Section 5. Specific OTC Requirements states that the labeling and Patient Information Leaflet for Voltarol Emulgel P will stipulate two weeks as the maximum period of unsupervised

use, with longer treatment only on advice of a doctor. The Society suggests that the wording is revised to include a reference to advice from a doctor or a pharmacist.

With reference to the provision of pharmacy training documents, the Society would support the comprehensive distribution of these materials which would give pharmacists adequate opportunity to engage with the information materials and be in a position to offer advice to customers about the product. Equally, broad dissemination of the product training documents would ensure that pharmacists who are not NPA members would also have access to training material.

The Society seeks feedback on the contents of the pharmacy training document and whether it will incorporate advice on how to deal with multiple pack purchases, given that the maximum proposed pack size will be 100g.

Package Leaflet

Introduction states that “you must contact a doctor if your symptoms worsen or do not improve within seven days” whilst it is indicated in Section 3 of the package leaflet that Voltarol Emulgel P should not be used for longer than fourteen days unless recommended by a doctor. The Society is concerned that customers may find this information confusing and seeks clarification on the safest duration of use. It may be worthwhile highlighting here the length of recommended treatment without a doctor’s intervention.

Section 2. Before you use Voltarol Emulgel P

The Society requests that the information detailing possible skin irritation and the ingredient Propylene Glycol be featured in this section of the package leaflet.

Bullet 3 states that Voltarol Emulgel P should not be used by those taking oral NSAIDs. The Society recommends that this advice is also included on the product packaging as customers may fail to note the wording on the package leaflet.

Section 5. How to store Votarol Emulgel P

As the pack size is being increased, the Society seeks information on how long an open pack remains efficacious.

We hope these comments are useful.

Thank you for contacting the Society.

Yours sincerely,

Dr. Catherine Duggan.

Director of Professional Development & Support.

