Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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Dear Ms. Alexander,

Re: Arm 65 – Request to Reclassify Algopain - Eze 140mg medicated plaster from POM to P

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 reclassification of Algopain – Eze140mg medicated plaster however we request that the following points are taken into consideration:

Reclassification Summary

Section 2. Product Details - Dosage including age-limits. The dosage details indicate that this product "is not recommended for use in children and adolescents below age 15". However the Society feels that this is inconsistent with the Package Leaflet (Section 3) which states "this medicine should not be used in children or adolescents" without stipulating any age limits.

The dosage section also states that the maximum total daily dose is two medicated plasters even if there is more than one injured area to be treated. However, the British National Formulary (Number 59, March 2010 p637) contains an entry for Voltarol Gel Patch (diclofenac epolamine - equivalent to 140mg diclofenac sodium per patch) stipulating a lower dose for ankle sprain i.e. 1 patch daily for up to 3 days.

Section 4.Specific OTC Requirements states that the UK label and leaflet will provide advice on not using the product with any other NSAID painkillers. The Society supports this statement and requests that it appears in the training material and is clearly highlighted at the start of the package leaflet and on the OTC packaging.

Section 4 makes reference to the development of a pharmacy training package specific to the UK to support OTC use of the product. The Society seeks clarification on the contents of the pharmacy training package.

Section 5. Safety Profile states that "there is agreement amongst authors that a small number of local skin reactions are associated with use of the medicated plasters; that systematic reactions are very rare, and that the rate of ADRs associated with the medicated plasters was not different to placebo".

The Society requests details of the original reference sources to hold on file for future enquiries.

Package Leaflet

Introduction states 'ask your pharmacist if you need more information or advice'. See comments above. The Society seeks feedback on the contents of the pharmacy training package and the information that pharmacy staff will be expected to provide.

Section 2. Before you use Algopain-eze 140mg medicated plaster.

Bullet 1 states "Do not use this medicine if you are hypersensitive (allergic) to diclofenac, propylene glycol, butylhydroxytoluene or any other ingredients in Algopain - Eze140 mg". The Society suggests cross-reference to Section 6 for a more comprehensive list of ingredients.

Bullet 5 states "Do not use this medicine on injured skin (e. g skin abrasions, cuts, burns), infected skin or eczema". The Society recommends that this advice is also included on the product packaging as customers may fail to note the wording in the package leaflet.

Bullet 6 states "Do not use this medicine during the last three months of pregnancy". However the section on 'pregnancy and breast-feeding' states "During the first six months of pregnancy, you should only use this medicine after speaking to your doctor". The Society is concerned that customers may find the information confusing and suggests that the advice concerning use in pregnancy during the first six months is made clearer.

Section 3. How to use Algopain–Eze 140mg medicated plaster states "Always use this medicine exactly as your doctor has told you to or according to the Package Leaflet". As the product will have been an OTC purchase, the purchaser may not have had any contact with the doctor. The Society suggests that the wording is revised and makes reference to advice from a doctor or pharmacist.

Duration of Use states 'Do not use this medicine for longer than 3 days without your doctor's advice, however Section 6 (Further Information) highlights the possibility of 2, 5, 10 or 14 pack sizes. The Society is concerned that the availability of larger pack sizes may result in patient safety issues if the patients use the product for a longer duration without seeking the advice of a doctor or pharmacist.

We hope these comments are useful.

Thank you for consulting the Society.

Yours sincerely,

Dr, Catherine Duggan.
Director of Professional Development & Support.