

Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Dear Ms Popo,

Re: ARM 41 - Request to reclassify Naproxen 250mg Tablets from POM to P

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

The Royal Pharmaceutical Society of Great Britain is the 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. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society requests that the following points be taken into consideration:

Whilst reclassification enables consumers to have greater availability and choice, we have some concerns regarding potential serious side effects.

Reclassification Summary

Proposed indication is primary dysmenorrhoea (period pain) in women aged between 15 and 50 years. The British National Formulary (March 2007) states however that the POM version is not recommended for dysmenorrhoea in children under 16 years.

Section 3.1 – concern that some of the side effects cited are serious. Consideration should be given to highlighting major interactions with other medications. The CSM previously issued advice highlighting that the combination of a NSAID and low-dose aspirin may increase the risk of gastro-intestinal side-effects.

Section 5.0 – highlights that ‘warnings consistent with those required for the existing oral OTC NSAID, ibuprofen, will be included in the product information for naproxen 250mg’. The BNF however states that naproxen has more side-effects (especially gastro-intestinal) than ibuprofen.

Section 6.0 – the CHM has remarked that the applicant should put forward proposals to monitor the usage and safety profile of naproxen in the pharmacy setting with six monthly Periodic Safety Update Reports. The Society requests feedback on why PSUR reports are needed if the product is indeed considered to be safe.

Patient Information Leaflet

Section ‘Things to know before taking your medicine’ – subsections on ‘Do not take this medicine unless your doctor said you can’ and ‘Important information about some of the ingredients of this medicine’ should preferably appear earlier in the leaflet. The Society has concerns regarding the high number of medicines cited under ‘Talk to your doctor or pharmacist first, if you are taking any of these other medicines’.

Section ‘Side effects that might happen while taking your medicine’ – concern regarding length of list. Suggest that subsection on ‘driving and using machines’ is highlighted by including it earlier in the list

Section ‘What is in these tablets?’ – states that the tablets come in boxes of 3, 6, 8 or 9 tablets however the application refers to 3 days treatment (i.e. 9 tablets).

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Lead Pharmacist for Self-care