

Abiodun Aderogba
MHRA
Room 3-M
151 Buckingham Palace Road
London
SW1W 9SZ

2nd April 2013

Dear Abiodun

Re: ARM 85; Anusol Advance Ointment request to reclassify a product from P to GSL

We write on behalf of the Royal Pharmaceutical Society (RPS) to respond to the above consultation.

The RPS is the professional body for pharmacists in Great Britain. We represent all sectors of pharmacy in Great Britain and we lead and support the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the professions policies and views to a range of external stakeholders in a number of different forums.

The RPS does not support the reclassification of Anusol Advance ointment from P to GSL.

The patient information leaflet consistently advises patients to seek advice from a pharmacist or doctor. In non-pharmacy outlets where GSL medicines are sold, professional advice is not available. Pharmacy sale of GSL medicines have shown to be safe, as pharmacists and trained healthcare advisors are on hand to counsel the patient on their medicines.

In addition, we request that the following points be taken into consideration.

Patient information leaflet

Section 2: Before you use this medicine

In this section the patient is advised to talk to their pharmacist or doctor before using Anusol Advance ointment if the following applies to them:

- They have ever had a bad reaction to Anusol or any of its ingredients.
- They have fungal, viral or bacterial skin sores.
- They have rectal bleeding or if you are in doubt whether any bleeding you have experienced is caused by piles.
- If symptoms worsen or do not improve after you have used the medicine for 7 days.
- They are taking or using any other medicines including corticosteroids (a type of anti-inflammatory drug e.g. hydrocortisone). In this warning it advises show the bottle or pack to a pharmacist if the patient is not sure about the medicine that they are taking or using.

Appropriate advice on the use of this product cannot be given to individuals at non pharmacy outlets, whereas in a pharmacy, pharmacists and trained staff could ensure that patients are given appropriate advice and directed, where necessary to a health professional.

Section 3: How to use this medicine

This section provides the patients with information on how to use Anusol ointment. Pharmacies will have trained staff ready to advise and counsel patients on using this product, which will not be available from non-pharmacy outlets.

We hope these comments are useful. Our reply may be made freely available.

Thank you for contacting the Royal Pharmaceutical Society.

Yours Sincerely

A handwritten signature in cursive script, appearing to read 'Ramin'.

Rakhee Amin
Professional Support Pharmacist