

To: Clare Hedges
MHRA
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From: British Association of Dermatologists
4 Fitzroy Square
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CONSULTATION DOCUMENT: ARM 73 IBUSOL LOTION

REQUEST TO RECLASSIFY A PRODUCT FROM POM TO P

ALL RESPONDENTS MUST TICK ONE OF THE FOLLOWING BOXES

- ~ **My reply may be made freely available**
- ~ **I wish parts of my reply to remain confidential***
- ~ **I wish my reply to remain confidential***

*Please use the space below to explain why you feel the information in your reply should be treated as confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete

Explanation regarding why your response should remain confidential

Name: Dr Mike Tidman
Date: 14/03/2011

Signature:



COMMENTS:

This request by the MHRA for comments on the proposal that Ibusol lotion be reclassified from POM to P (consultation document: ARM 73 Ibusol Lotion) was responded to by the Therapy and Guidelines Sub-Committee of the British Association of Dermatologists.

Although there were no major objections to this proposal, concern was raised regarding the possibility of significant absorption of ibuprofen if this product was

applied up to 8 times daily onto inflamed skin. Depending on the absorption data, it might be necessary to display the same warnings as for OTC oral ibuprofen, including potential drug interactions, and the warning to limit the volume applied should be in bold type.

It should be noted that, with reference to the section in the Patient Information Leaflet on ~~Responsible~~ Behaviour in the Sun^q the British Association of Dermatologists recommends the use of a sunscreen with a SPF of at least 30.