

ANNEX 1

Response document for MHRA public consultation on the proposal to make Acnecide Face Gel and Acnecide Face Wash available from general sales outlets without prescription

Ref: ARM 98

Your details

Name: [REDACTED]

Position (if applicable): Regulatory Affairs Consultant

Organisation (if applicable): N/A

Email: [REDACTED]

1. Do you consider that Acnecide Face Gel and Acnecide Face Wash should be available as General Sale List (GSL) medicines?

Yes • **No** • Not sure •

Please provide any comments or evidence to support your response:

Having read all of the information in the consultation document, it is difficult to be entirely convinced that these products should be allowed a GSL status. It seems that there is still a case for the sale of both products under the direct supervision of a Pharmacist in order that the user gets appropriate advice prior to commencing use of both products. It should be noted that both products (with multiple indications) continue to remain Pharmacy Only

2. Do you have any specific comments on the leaflets or the labels provided in the public reclassification report for Acnecide Face Gel and Acnecide Face Wash?

1) The following warning appears on the labelling and PIL:

If your acne gets worse while using Acnecide face wash/Acnecide face gel or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice.

Comment

Consider reducing the time period to 8 weeks so that the user can seek the advice of a pharmacist or doctor in a timely manner in order to deal with the condition rather than waiting for 12 weeks.

The consultation document states that most treatments for acne take two to four months to produce their maximum effect. This suggests that 8 weeks is sufficient time for a user to decide if there is no improvement of the condition and seek further advice. It seems unnecessary to wait until 12 weeks.

2) The PIL states:

- If you get severe skin irritation at any time whilst using Acnecide Face Wash you should stop the treatment. If your skin does not recover after stopping treatment you should seek a doctor's advice.

Comment:

Is it reasonable to expect that a 12 year old can understand the difference between mild, moderate and severe skin irritation and if not, should the leaflet be updated with a clearer explanation?

2. Do you have any specific comments on the leaflets or the labels provided in the public reclassification report for Acnecide Face Gel and Acnecide Face Wash?

The Text **FOR USE ON THE FACE ONLY** should also appear in a box on the tube label and it should be inside a box so that it is prominent.
Consider adding 'FOR EXTERNAL USE ONLY' on the labelling.

3. Do you have any other comments on the reclassification?

If the reclassification status is granted, for adolescents between the ages of 12-15 years, should there not at least be some minimum parental/adult supervision of the user when using these products? Such supervision would at the very least ensure that a parent or adult is aware that the user is using the product(s) and is able to guide them in the use of the product if necessary or intervene in circumstances where it might be necessary for them to do so.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes • Partially* • **No**

*If partially, please indicate which parts you wish to remain 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.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gov.uk) to arrive by **30 May 2019**. Contributions received after that date cannot be included in the exercise.