Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

# Public Assessment Report

# Pharmacy to General Sale List Medicine Reclassification

# Acnecide Face 5% w/w Gel & Acnecide Face Wash 5% w/w Gel

# Benzoyl peroxide

# PL 10590/0069 & 10590/0070

# Galderma (UK) Limited

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## 1. About Acnecide Face Gel & Acnecide Face Wash

Acnecide Face Gel and Acnecide Face Wash are for the treatment of mild acne affecting the face in adults and adolescents aged 12 years and over.

Either product is initially applied once daily to the face at bedtime; after 2-3 days if well tolerated, the product may be used twice daily, in the morning and evening. For the face gel, a thin layer is applied to the skin. For the face wash, the product should remain on the skin for 1-2 minutes, before thorough rinsing with water.

If the acne gets worse while using Acnecide Face Gel/Acnecide Face Wash or if it does not improve within 12 weeks, the patient should seek the advice of a pharmacist or doctor who will be able to recommend alternative treatment for their acne.

`Acnecide Face' products are for use in treatment of mild acne which limited to the face only. Acnecide products are currently also available from pharmacies, and these products, in contrast to `Acnecide Face' products, may be used for mild to moderate acne affecting more extensive areas of the body.

**What is in Acnecide Face Gel & Acnecide Face Wash?**

Acnecide Face Gel and Acnecide Face Wash are both gels, one intended to be left on the face and the other intended to be used as a wash, kept on the face for 1-2 minutes before being rinsed off with water. They both contain 5% w/w of the active ingredient benzoyl peroxide.

Products currently available in general sales outlets for topical treatment (application to the skin) of spots or acne contain active ingredients such as nicotinamide, chlorhexidine gluconate, and zinc oxide. Traditional herbal registrations[1] are available containing tea tree oil.

Acnecide Face Gel and Acnecide Face Wash are the first products containing benzoyl peroxide to be available as GSL medicines.

**What are Acnecide Face Gel & Acnecide Face Wash used for?**

Acnecide Face products are for the treatment of mild acne affecting the face, when comedones (blackheads and whiteheads) predominate and there are few or no papules or pustules (acne spots and pimples) and no inflamed spots, in adults and adolescents aged 12 years and over.

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[1] A Traditional Herbal Registration (THR) is a product authorised in the UK under the simplified registration scheme for Traditional Herbal Medicinal Products. Such products are identified by a THR number.

**Who has made the proposal?**

The marketing authorisation holder (MAH)[2] for Acnecide Face Gel and Acnecide Face Wash (Galderma UK Limited) applied to make these products available through general sales outlets.

In addition to Acnecide Face Gel and Acnecide Face Wash, the MAH currently has marketing authorisations for Acnecide 5% w/w Gel and Acnecide Wash 5% w/w Gel with pharmacy (P) legal status which they intend to maintain, in addition to the proposed GSL products. These pharmacy (P) products are distinguishable from the GSL products primarily by having broader conditions of use (may be used for more severe acne on any part of the body affected) and by their product names.

**What is the view of the Commission on Human Medicines?**

The Commission on Human Medicines has advised that Acnecide Face Gel and Acnecide Face Wash can be available as GSL medicines. Views on the use of these medicines for the treatment of mild acne affecting the face in people aged 12 years of age and over were also sought at a meeting of the Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group (GRID EAG)[3]. The views of the GRID EAG were taken into consideration by CHM when they advised on the reclassification application.

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[2] A Marketing Authorisation Holder (MAH) is the company with legal authorisation to make the medicine available to patients.

[3] An Expert Advisory Group (EAG) supports the work of the CHM in particular area(s) of medicine. One of the areas which the GRID EAG has expertise in is dermatology.

## 2. Proposed terms of reclassification

**What are the details of this change?**

Acnecide Face Gel and Acnecide Face Wash will be available through general sales outlets for:

- topical use (application to the skin)
- adults and adolescents aged 12 years of age and over
- treatment of mild acne affecting the face, when comedones (blackheads and whiteheads) predominate and there are few or no papules or pustules (acne spots and pimples) and no inflamed spots
- initial application once daily at bedtime; after 2-3 days, if well tolerated, frequency of application may be increased to twice daily, in the morning and evening
- the face gel, applied as a thin layer; persons with a sensitive skin should apply once daily before going to bed
- the face wash contact time with the skin should be 1-2 minutes, before thorough rinsing with water

  If acne gets worse or it does not improve within 12 weeks, advice should be sought from a pharmacist or doctor.

  Acnecide Face Gel will be available in packs of 15g of gel and Acnecide Face Wash in packs of 50g of gel.

## 3. How was the proposal assessed for Acnecide Face Gel & Acnecide Face Wash being available as a General Sale List medicine?

The proposal for Acnecide Face Gel & Acnecide face Wash is for reclassification from P to GSL. For a medicine to be classified as GSL it must be demonstrated that it meets the GSL criterion, which is set out in the Human Medicines regulations 2012, regulation 62(5). This criterion is as follows:
`GSL may be appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise by or under supervision of a pharmacist.'

`Reasonable safety' is defined as `where the hazard to health and risk of misuse and need for special precautions in handling are small, and wider sale would be a convenience to the purchaser.'

## Assessment of suitability for availability in general sales outlets

A GSL medicine may be sold in general sales outlets in the absence of healthcare professional advice. It is important therefore, that a GSL medicine may be safely sold or supplied without need of a consultation with a doctor or pharmacist.

### Hazard to health

The safety of benzoyl peroxide, the active ingredient in Acnecide Face Gel and Acnecide Face Wash is well established. It has been prescribed for topical treatment of acne since the 1960's; products containing this active ingredient are available in 70 countries worldwide. In the UK, Acnecide 5% w/w Gel was approved as a pharmacy (P) medicine in 1992 and Acnecide Wash 5% w/w Gel as a pharmacy medicine in 2002.

The majority of adverse effects (side effects) reported for Acnecide Gel and Acnecide Face products are skin reactions including very commonly (affecting 1 in 10 or more of patients) dryness, redness, peeling and burning sensation and commonly (affecting 1 in 100 or more, but fewer than 1 in 10 patients) itchiness, pain, stinging and irritation. Less commonly, allergic contact dermatitis (development of allergy due to contact of the skin with the product) may occur.

The proposed instructions for using Acnecide Face Gel and Acnecide Face Wash as a GSL medicine take account of the irritant effects that benzoyl peroxide has on the skin. The proposed instructions are to start using the Face Gel or Face Wash once daily increasing to twice daily if irritation can be tolerated. If excessive irritation occurs, the patient is advised to reduce use to once daily or on alternative days or temporarily stopping application until the skin recovers. If severe irritation occurs, the patient is advised to stop use of the product altogether. If skin does not recover after stopping use, the patient is advised to consult their doctor.

Hypersensitivity reactions and anaphylactic reactions (severe allergic reactions) may occur with use of Acnecide preparations. Such reactions are idiosyncratic in their nature (occur rarely and unpredictably amongst the patient population) and are no more likely to occur in the GSL setting than with the current `Acnecide' preparations available form pharmacies. The patient information leaflets for Acnecide Face Gel and Acnecide Face Wash advise the patient to seek immediate medical attention if they experience symptoms of severe allergic reaction (raised itchy rash, swelling of the face, eyes, lips, tongue or mouth, difficulty breathing).

Effects on skin colour known as pigmentation disorders, for example, areas of darkened skin (hyperpimentation) or areas of lightened skin (hypopigmentation) have been identified as possible safety signals (information on new or known adverse events that are potentially caused by a medicine) requiring closer monitoring for `Acnecide' products. It is not clear whether such disorders are due the active ingredient (benzoyl peroxide) or due to acne itself.

A risk associated with treatment of acne in the GSL setting is that of delay in seeking professional advice and more appropriate treatment when necessary. This may be the case when acne is more widespread than on the face only or is moderate to severe, in which case Acnecide Face Gel and Acnecide Face Wash

would not be appropriate. There may also be delay in receiving more appropriate treatment where the patient starts treatment for their mild acne on the face with Acnecide Face Gel or Acnecide Face Wash, but their acne does not improve or is worsening.

It is essential for the GSL setting therefore that the patient is:
- able to identify whether their acne is suitable for treatment with Acnecide Face Gel or Acnecide Face Wash; therefore, be able to distinguish mild acne from moderate to severe acne
- given clear information about what to do if the product is not effective
- given clear information about the importance of seeking professional advice in cases where acne may be progressing, since under-treatment of certain forms of acne may result in scarring

The risk of using the products for more severe or widespread acne or delay in receiving more appropriate treatment where required, is managed in the patient information for Acnecide Face Gel and Acnecide Face Wash, which includes the following:

Patient information leaflet (PIL)

- statement that the product is suitable for mild acne which is limited to the face only
- clinical images of mild, moderate and severe acne to help the patient distinguish between these forms of acne
- detailed and prominent (emboldened) warning `If your acne gets worse while using Acnecide Face Gel/ Acnecide Face Wash or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Undertreatment of some forms of acne may sometimes result in scarring. Your pharmacist or doctor will be able to recommend an alternative treatment for your acne.'

Label (outer carton)

- an image of mild acne (consistent with that in the PIL)
- a statement `For the treatment of mild acne of the face'
- a warning `If your acne gets worse while using Acnecide Face Gel/ Acnecide Face Wash or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Undertreatment of some forms of acne may sometimes result in scarring. Your pharmacist or doctor will be able to recommend an alternative treatment for your acne.'

The proposed duration of treatment of 12 weeks during which to assess if Acnecide Face Gel or Acnecide Face Wash are having the desired effect for the patient is considered acceptable. In general, most treatments for acne take two to four months to produce their maximum effect. As noted above, the patient information provides advice about what to do if acne is not responding to treatment or if it is worsening.

The proposed pack sizes of 15g for the face gel and 50g for the face wash are suitable and in line with the proposed method of application to the face and initial treatment period of 12 weeks.

## Risk of misuse

*Incorrect use*
There is little risk of Acnecide Face Gel and Acnecide Face Wash being used incorrectly. The proposed instructions for using the products as GSL medicines take account of the irritant effects that benzoyl peroxide has on the skin, advising stepwise increase in application from once to twice daily. If excessive irritation of the skin occurs, reducing application to once daily or on alternative days is recommended. Excessive use of the products in an attempt to improve efficacy will increase irritant effects that benzoyl peroxide has on the skin, including peeling and redness.

*Masking a more sinister condition*
There is little risk of a more sinister condition being masked as a result of using these products. Acne is a well-recognised condition and medicinal products are already available as GSL to treat it.

*Abuse/addiction potential*
The active ingredient benzoyl peroxide is not considered to be a compound associated with abuse or addiction potential. There is no known illicit use of this substance. It is intended to be applied to the skin for local action only, its absorption from the skin into the body is low and it does not accumulate in body tissues.

## Special precautions in handling

There are no special handling requirements for Acnecide Face Gel and Acnecide Face Wash that would prevent their availability as GSL medicines.

## Role of the pharmacist

The proposed condition (mild acne affecting the face) for which Acnecide Face Gel/Acnecide Face Wash are intended to be used, is one which is already being treated by patients in the GSL setting, in absence of healthcare professional advice. Acne is a well-recognised condition, experienced in varying degrees of severity, by the majority of the population during their teens.

Use of Acnecide Face Gel/Acnecide Face Wash in the GSL setting is limited to mild acne affecting the face. To address concerns regarding worsening of acne and potential delay in seeking more appropriate treatment, as a risk minimisation measure, the product information gives the patient relevant precautions, warnings and advice (see `Hazard to Health' above).

## Convenience to the purchaser

Availability of Acnecide Face Gel and Acnecide Face Wash under the conditions proposed would provide additional choice for the patient in the GSL setting for treatment of mild acne affecting the face.

## 4. Further details on the application

**Risk Management Plan**
The application contains a risk management plan (RMP) which was required when the product was first authorised. The RMP documents the following:

- the known safety profile of the medicine, including any important identified and potential risks
- what is not known about the safety profile (`missing information')
- how the safety profile will be monitored after the medicine is licensed, including any plans for further studies to actively gain more knowledge about the safety of the medicine (`additional pharmacovigilance activities')
- how any important risks will be prevented or minimised in patients (`risk minimisation measures') and how the usefulness and effectiveness of the risk minimisation measures will be assessed

The RMP for Acnecide Face Gel and Acnecide Face Wash has identified the main risks associated with the products if classified as GSL and proposes how these will be managed. Close monitoring of serious allergic reactions and pigmentation disorders (see section 3 `Hazard to Health' above) are proposed. Otherwise, routine pharmacovigilance (monitoring and reporting of adverse events for a medicine, for which there are no special safety concerns) and risk minimisation via the product information (SmPC, labelling and patient information leaflet) are proposed for these products in the GSL setting.

**Label and leaflet**
The patient information leaflets and labels are provided in Annex 2 and 3.

**Summary of Product Characteristics**
The Summaries of Product Characteristics are provided in Annex 4. These documents are descriptions of the properties of Acnecide Face Gel and Acnecide Face Wash and the conditions attached to their use. They are used as references by healthcare professionals.

## 5. Consultation on GSL availability

Consultation document ARM[1] 98, which summarises the proposal for pharmacy to general sale list (P to GSL) reclassification of Acnecide Face Gel and Acnecide Face Wash was posted on the GOV.UK website on 9 May 2019. The deadline for comments was given as 30 May 2019. ARM 98 can be accessed at the following link:

https://www.gov.uk/government/consultations/consultation-on-acnecide-face-gel-and-face-wash

[1] ARM stands for Application to Reclassify a Medicine. An ARM consultation is a public consultation inviting views from all stakeholders on a proposal to reclassify a medicine from POM to P or P to GSL.

8 responses were received. 4 responses (from patients/members of the public) were in favour of the reclassification. 4 responses (2 from professional bodies/associations representing pharmacists, 1 from a pharmacy trade body and 1 from a pharmaceutical company regulatory affairs consultant) were not in favour.

### 5.1 Responses agreeing with the proposal to reclassify Acnecide Face Gel & Acnecide Face Wash as General Sale List (GSL) medicines

4 responses in favour of reclassification were received with some of the comments as follows:

- I have used Acnecide for acne outbreaks on the cheeks for over 6 years without any problems or side effects.
- The availability at outlets other than pharmacies would be convenient, as pharmacies are not nearby.
- I have tried dozens of spot treatments and none worked until Acnecide Face gel; this has been a big boost to my self-esteem.
- I order Acnecide online as the price in the pharmacy can be quite high; increased availability in other shops may result in lower price overall.
- I have used Acnecide Gel since 2015 and it has made a terrific improvement to my life and my acne, which is now limited to occasional hormonal outbreaks that the gel helps clear quickly.
- I have always found it completely safe to use and have experienced no side effects.
- It is important to sufferers that they can buy a truly effective product with ease when they desperately need it but may not have easy access to a pharmacy.
- The proposed labelling is correct and helpful.
- Everyone's skin responds differently to treatment, but if I had found this product in stores earlier when I began to have problems, I could have saved myself years of unhappiness and disappointment.

### 5.2 Responses disagreeing with the proposal to reclassify Acnecide Face Gel & Acnecide Face Wash as General Sale List (GSL) medicines

Comments from professional bodies/associations (2), a trade body and an industry consultant included the following:

a) *Directions for usage are complicated and people would benefit from advice of a trained member of the pharmacy staff supervised by a pharmacist on instructions for use, managing the condition and potential side effects.*

The directions for use provided in the patient information leaflet clearly set out the stepwise approach to use of the products, increasing frequency of use to twice daily, once tolerance to the irritant effects of benzoyl peroxide is achieved. In contrast, if the effects of benzoyl peroxide are not well tolerated or if severe irritation of the skin occurs, the patient is advised to stop using the product and if the skin does not improve, to seek the advice of a doctor.

To provide further clarity for the patient regarding use of the product and potential side effects, the following amendments to the patient information have been made:

Leaflet

At the head of section 3 (How to use Acnecide Face Wash/Face Gel) an emboldened statement has been added which informs the patient about the irritant effects of benzoyl peroxide and therefore, the need for gradual stepwise introduction to use if the product to see how it affects them before increasing frequency of use to twice daily. This is followed by information stressing the importance of stopping the product and the need to seek healthcare professional advice in cases where the product causes severe skin irritation which has not settled down despite having stopped usage.

b) *Reliance is on the individual to self-diagnose mild acne and differentiate this from moderate to severe forms. It is unlikely that many patients suffering from acne will be able to distinguish the degree of their condition. If the product is used for moderate or severe acne there is risk of a delay in receiving the appropriate treatment.*

Products are currently available in the GSL setting for the treatment of mild to moderate acne. The applicant's original proposal for GSL use of Acnecide Face Gel/Face Wash was for `mild to moderate acne' affecting the face. The CHM noted the views of external experts (GP's with special intertest in dermatology/dermatologist) and those of its expert advisory group (GRID EAG) with expertise in dermatology and advised to limit the use of the product to `mild acne' of the face providing that the patient information conveyed the following information:

- The headline section of the leaflet should clearly state that the product is for treatment of mild acne limited to the face only.
- To minimise the risk of scarring due to undertreatment of acne, detailed and prominent information should be provided about what to do if the product is not effective and the importance of seeking professional advice in cases where acne may be progressing.
- To ensure the patient is able to identify the condition for which the product is intended to be used, pictures/images of acne should be included which distinguish mild acne from moderate to severe acne.

The proposed patient information leaflet/label include the above information further to CHM advice. In addition to images of acne, the patient information leaflet includes a description of mild acne (predominantly blackheads and whiteheads, few or no spots or pimples and no inflamed spots).

Following consideration of responses to public consultation, further improvement of the patient information was made as follows:

Leaflet

Text in the headline section was emboldened to emphasise the product is for

`mild acne' affecting the `face only'. The warning `If your acne gets worse while using Acnecide Face Gel/Face Wash or if it does not improve within 12 weeks, it is important that you see your pharmacist or doctor for advice. Under treatment of some forms of acne may result in scarring. Your pharmacist or doctor will be able to recommend an alternative treatment for your acne', in addition to being emboldened has been enclosed in a rectangular box, to improve prominence of this key safety information.

Outer carton

For the product outer carton, consideration was given to including images of moderate to severe acne, in addition to that of mild acne to help the patient distinguish more readily between the forms of acne and as an aid in determining if the product is suitable for them at point of sale.

The applicant has provided suitable justification for not providing further images of acne on the product outer carton as follows:

- to accommodate further images on the carton would compromise legibility/readability of other key safety information for the product
- multiple images of acne would be smaller than the single image of mild acne; the differences between the different images would not be clearly legible
- the outer carton has already been modified to accommodate the key safety information for the product and is therefore already much larger than the immediate packaging (internal tube)
- the other key safety information provided on the carton is considered sufficient for the patient to decide on suitability of the product at point of sale

A statement has been included in bold text advising patients with moderate to severe/more extensive (not limited to the face) acne to speak to their pharmacist who will be able to advise them regarding treatment of their acne. The words `mild acne' and `face' have been emboldened in the statement on the rear face of the carton so that they are more prominent.

These further amendments to the patient information are considered to address the concerns of respondents to consultation and further strengthen advice issued by the CHM.

c) *Skin reactions commonly occur, and people should be advised of this. There are also side effects which require closer monitoring. If sold from the pharmacy, the patient has opportunity to discuss any side effects with the pharmacist. Managing even minor side effects should be discussed with the pharmacist, even stepping down usage to alternate days; it may be appropriate for the person to stop Acnecide and not re-start it. Community pharmacists are well positioned to provide the advice and support to the customer, including side effects, potential interactions and usage advice.*

Amendments to the PIL (see `a' above) have been made in respect of need for stepwise use of the product to determine tolerability to benzoyl peroxide and to

minimise side effects, particularly when treatment is being initiated. Section 4 (`Possible side effects) of the PIL is consistent with the marketing authorisation, listing side effects which the patient may experience along with frequency of occurrence. Allergic contact dermatitis has been defined more clearly for the patient. In addition, the statement `If your skin becomes severely irritated, or severe redness, itching or peeling of the skin occurs, discontinue use immediately and consult your pharmacist or doctor' has been emboldened for increased prominence.

Concerning effects on the skin which require closer monitoring (areas of darkened or lightened skin), these have been identified as being potentially due to use of Acnecide products. These effects may also be due to acne itself; a causal link with Acnecide products is unclear. On-going monitoring of these potential effects will provide more evidence. If required by new evidence, the marketing authorisations for Acnecide products will be revised and updated information provided for the patient in the leaflets for the products.

d) *Acne can have a severe psychological impact on an individual's mental health, so initial and regular interaction with a health professional would provide an opportunity for this to be spoken about and for signposting to other services as necessary. Even mild and moderate forms of the condition can lead to severe distress and behaviour change which can require referral to appropriate services. The opportunity to make an intervention will be lost in settings without trained staff available. Community and online pharmacies provide the vast majority of the population with access to these medications.*

Acne is a condition which is already being treated by patients in the GSL setting without healthcare professional advice. The individuals responding to this consultation welcomed the proposed availability of this product in the GSL setting for various reasons, including ease of access (see section 5.1).

It is acknowledged that acne, even if mild to moderate can have a psychological impact, which may be severe, in some individuals. In such cases, regular contact with a healthcare professional and referral to appropriate services is necessary.

To address this concern, the patient information was revised as follows:

Leaflet

In the warnings and precautions section, the statement `If you are worried or upset about your acne, even if it is mild, you should consult your doctor or pharmacist for advice' was emboldened. In addition to increased prominence of this warning, further information regarding the psychological effects of acne and the need to seek professional advice was included as follows:

'Acne can be associated with increased risk of depression, anxiety, poor self-image and poor esteem. If you experience any of these psychological effects, please consult your doctor for professional advice.'

e) *The outer carton provides an image of mild acne only and not comparator images (moderate to severe acne); nor does it advise the consumer what to do if their acne appears to be worse than mild acne.*

The outer carton has been revised to include a statement in bold text advising the patient to consult their pharmacist for treatment advice in cases where acne is moderate/severe/more extensive than on the face only. The applicant has provided suitable justification for not including additional images of acne on the outer carton (see b) above).

f) *Consider reducing the time period for use before seeking further advice if the product is not working from 12 weeks to 8 weeks. It seems unnecessary to wait 12 weeks.*

12 weeks falls halfway between 2 to 4 months (8 to 16 weeks), the period for which in general, it takes most acne treatments to have their maximum effect.

The patient information leaflet and outer carton label for Acnecide Face products give clear information for the patient regarding what to do if their acne is not responding or is worsening within 12 weeks (seek healthcare professional advice). The patient information does not imply that the patient must persevere for 12 weeks before considering alternative treatment options/ seeking professional advice.

g) *The PIL states -If you get severe skin irritation at any time whilst using Acnecide Face Wash/Gel you should stop the treatment. If your skin does not recover after stopping treatment, you should seek a doctor's advice. Is it reasonable to expect a 12-year old to understand the difference between mild, moderate and severe skin irritation and if not, should the leaflet provide a clearer explanation?*

The PIL clearly advises the patient what to do in the event that they experience severe irritation of the skin; this is in addition to providing clear information regarding the irritant effects which benzoyl peroxide may have and the need for stepwise increase/decrease in frequency of application of the products accordingly.

12-year olds and young adolescents are likely to consult with their peers and the internet about treatment of their acne, and this may be in addition to consulting a professional or parent for advice. They are considered able to understand and act on the information provided in the leaflet for Acnecide products.

h) *For adolescents between the age of 12 – 25 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) 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.*

Use of this product in the GSL setting does not preclude any parental/adult supervision which may be available to young patients should they wish to have it.

## 6. Advice from the CHM

CHM considered the reclassification application and advised in favour of GSL availability of Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel under the conditions outlined above – for the treatment of mild acne affecting the face in adults and adolescents aged 12 years and over.

## 7. Conclusion

Assessment of the responses to consultation on the application to reclassify Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel to GSL legal status revealed no new issues of concern in addition to those considered by the CHM. Further amendments to the patient information (PIL and label) for these products have been made to address concerns raised by respondents to the public consultation.

Considering the advice from the CHM and further amendments made to the patient information, the MHRA has taken the decision to approve GSL legal status for Acnecide Face 5% w/w Gel and Acnecide Face Wash 5% w/w Gel.

## 8. Further information

The summaries of product characteristics and patient information leaflets are available on the MHRA website:

http://www.mhra.gov.uk/spc-pil/

The responses to consultation are published here: