

**QV WASH  
PL 18278/0004**

**UKPAR**

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**QV WASH**  
**PL 18278/0004**

**LAY SUMMARY**

The MHRA today granted Ego Pharmaceuticals (UK) Limited a Marketing Authorisation (licence) for the medicinal product QV Wash (PL 18278/0004). This is a general sales licence (GSL) for use as a soap alternative for the treatment of dry, scaly skin associated with ichthyosis, xerosis, pruritus hiemalis, sun-damaged skin and allergic dermatitis and for the temporary relief of symptoms of atopic or infantile eczema and psoriasis.

QV Wash contains the active ingredient glycerol.

No new or unexpected safety concerns arose from these applications and it was therefore judged that the benefits of using QV Wash outweighed the risks, hence a Marketing Authorisation has been granted.

**QV WASH  
PL 18278/0004**

**SCIENTIFIC DISCUSSION**

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## **INTRODUCTION**

Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product QV Wash to Ego Pharmaceuticals (UK) Limited (PL 18278/0004) on 24<sup>th</sup> August 2006. The product has a general sales licence (GSL).

The application was submitted as an abridged application according to Article 10a of Directive 2001/83/EC, a bibliographic application.

The product contains the active ingredient glycerol and is indicated for use as a soap alternative for the treatment of dry, scaly skin associated with ichthyosis, xerosis, pruritus hiemalis, sun-damaged skin and allergic dermatitis and for the temporary relief of symptoms of atopic or infantile eczema and psoriasis.

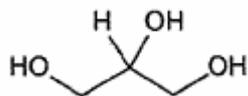
Glycerol is an emollient.

## PHARMACEUTICAL ASSESSMENT

### DRUG SUBSTANCE

RINN                      Glycerol

Structure:



Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis. A comprehensive risk assessment has been performed on the active substance such that a certificate of suitability is not required and it can be assumed that the glycerol produced is not susceptible to TSE.

An appropriate specification is provided for the active substance glycerol.

Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Appropriate proof of structure has been supplied for the active pharmaceutical ingredient.

All potential known impurities have been identified and characterised.

Batch analysis data are provided that comply with the proposed specification.

The container used for storage of the active substance is satisfactory.

Appropriate stability data have been generated and no indication of instability seen. The data support a retest period of 12 months.

### DRUG PRODUCT

#### Other ingredients

Other ingredients consisted of pharmaceutical excipients citric acid anhydrous, disodium cocoamphodiacetate, ethylene glycol monostearate, lauryl betaine, PEG-120 methyl glucose dioleate, sodium cocoyl isethionate, sodium lauryl sulphate, water purified, methyl hydroxybenzoate and propyl hydroxybenzoate. With the exception of disodium cocoamphodiacetate, ethylene glycol monostearate, lauryl betaine, PEG-120 methyl glucose dioleate, sodium cocoyl isethionate, sodium lauryl sulphate (which all comply with suitable in-house specifications), all excipients used comply with their Ph Eur monograph.

Satisfactory certificates of analysis have been provided for all excipients. None of the excipients used contain material of animal or human origin.

**Manufacture**

A satisfactory description and flow-chart of the manufacturing method has been provided. The process uses standard pharmaceutical equipment and technology in a conventional manner.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out on full-scale batches of the product. The results appear satisfactory.

**Bioavailability**

There are no bioavailability studies as the product is intended for topical application. As the active ingredient does not require systemic absorption for its effect. Consequently, this omission is acceptable.

**Finished product specification**

The finished product specification is satisfactory. Test methods have been described and have been adequately validated as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis have been provided for any working standards used.

**Container Closure System**

Specifications and Certificates of Analysis for the primary packaging material have been provided. These are satisfactory. All primary packaging is controlled to Ph Eur standards. The finished product is presented in pack sizes of 15ml, 200ml, 240ml, 500ml and 1000ml.

**Stability**

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 24 months has been set with the precaution "Do not store above 25 degrees", which is satisfactory.

**Conclusion**

It is recommended that a Marketing Authorisation is granted for this application.

## **PRECLINICAL ASSESSMENT**

As this is a bibliographic application containing an active substance (glycerol) that has been used in products for over 20 years, it was not considered necessary to perform a preclinical assessment.

## **CLINICAL ASSESSMENT**

### **1. INDICATIONS**

QV Wash cutaneous solution is a soap alternative for the treatment of dry, scaly skin associated with ichthyosis, xerosis, pruritus hiemalis, sun-damaged skin and allergic dermatitis. For the temporary relief of symptoms of atopic or infantile eczema and psoriasis.

Suitable for use in infants and the elderly.

The indications are satisfactory for a product of this type.

### **2. DOSE & DOSE SCHEDULE**

For cutaneous use. QV Wash can be used as often as required in the shower or at the hand basin. Wet skin and apply a small amount of QV Wash to the affected area. Lightly massage onto skin. Rinse and gently pat dry.

### **3. TOXICOLOGY**

No new data submitted

### **4. CLINICAL PHARMACOLOGY**

No new data submitted

### **5. EFFICACY**

No data submitted

### **6. SAFETY**

No data submitted

### **7. EXPERT REPORTS**

A comprehensive clinical expert report written by an appropriately qualified physician has been submitted.

### **8. PATIENT INFORMATION LEAFLET (PIL)**

Satisfactory.

### **9. LABELLING**

Satisfactory.

### **10. APPLICATION FORM (MAA)**

Satisfactory.

### **11. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)**

Satisfactory.

### **12. MEDICAL CONCLUSION**

It is recommended that a Marketing Authorisation be granted.

## **OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT**

### **QUALITY**

The important quality characteristics of QV Wash are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

### **PRECLINICAL**

No new preclinical studies were conducted. The preclinical data submitted have not revealed any evidence of potential risks to human health from use of QV Wash.

### **EFFICACY**

No new or unexpected safety concerns arise from this application.

The SPC and PIL are satisfactory and consistent with that for the reference products.

### **RISK BENEFIT ASSESSMENT**

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Extensive clinical experience with glycerol is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

**QV WASH  
PL 18278/0004**

**STEPS TAKEN FOR ASSESSMENT**

1	The MHRA received the marketing authorisation application on 15 <sup>th</sup> September 2000
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 26 <sup>th</sup> September 2000
3.	Additional clinical information was requested on 26 <sup>th</sup> April 2001 and additional pharmaceutical information was requested on 23 <sup>rd</sup> May 2001
4.	Additional pharmaceutical and clinical information was provided on 11 <sup>th</sup> October 2002
5.	Further pharmaceutical information was requested from the applicant on 20 <sup>th</sup> February 2003 and 28 <sup>th</sup> May 2004
6.	Further pharmaceutical information was provided on 3 <sup>rd</sup> September 2003 and 21 <sup>st</sup> August 2006
7.	The application was determined on 24 <sup>th</sup> August 2006

**QV WASH  
PL 18278/0004**

**STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

<b>Date submitted</b>	<b>Application type</b>	<b>Scope</b>	<b>Outcome</b>

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. Trade Name of the Medicinal Product

QV Wash

### 2. Qualitative and Quantitative Composition

Glycerol 10% w/w

For excipients see 6.1

### 3. Pharmaceutical Form

Cutaneous solution

White to off-white, smooth, milky translucent pearlescent lotion

## 4 CLINICAL PARTICULARS

### 4.1. Therapeutic Indications

QV Wash cutaneous solution is a soap alternative for the treatment of dry, scaly skin associated with ichthyosis, xerosis, pruritus hiemalis, sun-damaged skin and allergic dermatitis. For the temporary relief of symptoms of atopic or infantile eczema and psoriasis. Suitable for use in infants and the elderly

### 4.2. Posology and Method of Administration

For cutaneous use.

QV Wash can be used as often as required in the shower or at the hand basin. Wet skin and apply a small amount of QV Wash to the affected area. Lightly massage onto skin. Rinse and gently pat dry.

### 4.3. Contra-indications

Hypersensitivity to any of the ingredients of the preparation.

### 4.4. Special Warnings and Precautions for Use

Avoid contact with the eyes. If QV Wash enters the eyes, flush with clean water.

QV Wash is for topical use only.

QV Wash contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

If the condition does not improve or is aggravated, discontinue use and consult a doctor.

### 4.5. Interactions with other Medicaments and other forms of Interaction

No known interactions.

### 4.6. Pregnancy and Lactation

There is no evidence of the safety of QV Wash in human pregnancy and lactation. However, the constituents of the preparation have been in wide use for many years without apparent ill consequences.

### 4.7. Effects on Ability to Drive and Use Machines

Not applicable.

### 4.8. Undesirable Effects

No known undesirable effects.

### 4.9. Overdose

No case of overdose has been reported

**5 PHARMACOLOGICAL PROPERTIES****5.1. Pharmacodynamic Properties**

Pharmacotherapeutic group: Other emollients and protectives, ATC code: D02A C

QV Wash is a humectant cleansing treatment that is free from fragrances, colouring agents and potential irritants. It contains glycerol that has humectant and emollient properties. The hydrating effect of the product helps restore the moisture content of the stratum corneum and to counteract the drying effect of cleansing agents thus keeping the skin soft and pliable.

**5.2. Pharmacokinetic Properties**

For local application only.

**5.3. Preclinical Safety Data**

Glycerol is a well-established emollient remedy. It has been safely and effectively used in topical applications for a number of decades.

**6 PHARMACEUTICAL PARTICULARS****6.1. List of Excipients**

Citric acid, anhydrous  
Disodium cocoamphodiacetate  
Ethylene glycol monopalmitostearate  
Lauryl betaine  
PEG-120 methyl glucose dioleate  
Sodium cocoyl isethionate  
Sodium lauryl sulphate 30% w/w solution  
Purified water  
Methyl parahydroxybenzoate (E218)  
Propyl parahydroxybenzoate (E216)

**6.2. Incompatibilities**

None known.

**6.3. Shelf Life**

2 years.

**6.4. Special Precautions for Storage**

Do not store above 25°C

**6.5. Nature and Contents of Container**

200mL, white HDPE bottles fitted with flip-top white polypropylene caps.  
240mL white HDPE bottles with membrane plug caps and shower hanger cover  
500mL, 1L white HDPE bottles fitted with polypropylene pumps  
15ml white HDPE bottle fitted with polypropylene screw cap as sample pack

**6.6. Instruction for Use/Handling**

No special requirements.

**7. MARKETING AUTHORISATION HOLDER**

Ego Pharmaceuticals (UK) Limited  
15 Windsor Park, 50 Windsor Avenue,  
Merton,  
London SW19 2TJ  
United Kingdom.

8. **MARKETING AUTHORISATION NUMBER**  
PL 18278/0004
- 9 **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**  
24/08/2006
- 10 **DATE OF REVISION OF THE TEXT**  
24/08/2006

QV Wash Patient Information Leaflet		
Ego Version 10	Prepared: June 2006	Country: UK

## Patient Information Leaflet

### QV Wash

(Glycerol)

Please read this information carefully before you start to use QV Wash as it has been prepared to tell you about the product and to help you use it correctly. However, it does not contain all the available information about QV Wash, so if you have any further questions, please ask your doctor or pharmacist.

Please keep this leaflet in a safe place as you may wish to look at it again while you are using QV Wash.

#### **The name of your product is QV Wash**

QV Wash is a white to off-white, smooth, milky, translucent pearlescent lotion for use only on the skin. The active ingredient is Glycerol 10%w/w.

The other ingredients are citric acid anhydrous, disodium cocoamphodiacetate, ethylene glycol monopalmitostearate, lauryl betaine, PEG-120 methyl glucose dioleate, sodium cocoyl isethionate, sodium laurilsulfate, purified Water, methyl parahydroxybenzoate (E218), and propyl parahydroxybenzoate (E216)

*pH 6: The pH of your skin is 6. QV Wash is manufactured at this pH to be mild and gentle on the skin.*

QV Wash is free from lanolin, perfume and colour to avoid further irritation to people who may be sensitive to these ingredients.

QV Wash is available in 200 mL, 240 mL, 500 mL and 1 litre bottles. A 15ml sample pack is also available

#### **About QV Wash**

QV Wash is a cleansing treatment that contains 10% glycerol, an emollient with moisturising properties. Emollients such as glycerol have a hydrating effect and are effective in reducing the dryness of the skin and in counteracting the drying effects of cleansing agents.

#### **Marketing Authorisation Holder**

Ego Pharmaceuticals (UK) Limited,  
15 Windsor Park,  
50 Windsor Avenue,  
Merton, London, SW19 2TJ  
United Kingdom.

#### **Manufacturer**

Crawford Healthcare Limited  
Cheshire House,  
164 Main Road, Goostrey  
Cheshire, CW4 8JP  
United Kingdom

PL18278/0004

#### **What is QV Wash for**

QV Wash is a soap substitute for use on dry skin. QV Wash provides relief to itchy and dry skin by soothing and softening the skin.

QV Wash is recommended for treatment of dry, scaly skin in a wide range of dry skin conditions such as ichthyosis (scaly skin), xerosis (dry skin), pruritus hiemalis (chapping of the skin in cold conditions), allergic dermatitis, sun damaged skin. For temporary relief of symptoms of atopic or infantile eczema and psoriasis.

#### **Before you use QV Wash**

**Before you use QV Wash, please note;**

**Important information about some of the ingredients of QV Wash:** QV Wash contains propyl hydroxybenzoate (E216) and methyl parahydroxybenzoate (E218) which may cause allergic reactions, possibly delayed.

Check the list of ingredients stated above. If you are sensitive (have allergies) to any of them do not use this product.

**Pregnancy, breast feeding:** If you are breast feeding or pregnant or are thinking of starting a family, please talk to your doctor before starting QV Wash

**Driving and using machinery:** QV Wash will not affect your ability to drive or operate machinery

QV Wash Patient Information Leaflet		
Ego Version 10	Prepared: June 2006	Country: UK

**Taking other medicines:** Please inform your doctor or pharmacist if you are using or taking any other medicines or creams, even those not prescribed.

**If you are not sure about using QV Wash then please talk to your doctor or pharmacist.**

### Advice when using QV Wash

Follow this advice when using your QV Wash, if you need any further information talk to your doctor or pharmacist.

- Keep the QV Wash away from the eyes. If it accidentally gets into the eyes, flush them with clean water.
- As soap can irritate skin, you may benefit from using this soap substitute rather than ordinary soap on dry areas of skin. QV Wash can be used in the shower or hand basin.

If your skin problem becomes worse or you have a reaction, stop using QV Wash and tell your doctor or pharmacist immediately.

### How to use QV Wash

For use on the body, face and hands.

### For External Use Only

QV Wash should be used as a soap substitute, especially while showering, bathing and shaving.

- Wet skin and apply a small amount of QV Wash to the affected area.
- Lightly massage onto skin.
- Rinse and pat dry.
- Replace the cap after use.

### After using QV Wash

QV Wash is very effective and most people do not usually have any problems. If you experience any irritation or any other unwanted effects then stop using the wash and tell your doctor.

QV Wash may not work immediately, however if your condition does not improve you should tell your doctor.

If you follow the instructions for use, it should not be possible to use too much. If QV Wash is accidentally swallowed, you should contact your doctor immediately.

**If you are not sure about using QV Wash, please talk to your doctor or pharmacist.**

### Storing QV Wash

- Do not store above 25°C
- If the "expiry date" on the label has passed, stop using QV Wash and dispose of it safely, such as by giving it to your pharmacist.
- You should never give your QV Wash to anyone else to use, even if they appear to have the same symptoms as you.
- Always keep QV Wash in a safe place out of the reach and sight of children.

### Further Information

Further information is available from your doctor and pharmacist

Date of preparation: June 2006

15 Millilitre Pack



The batch number and expiry date are printed on the base of the carton, as stated on the label.



The batch number and expiry date are printed on the base of the bottle, as stated on the label.

200 Millilitre Pack



The batch number and expiry date are printed on the base of the carton, as stated on the label.

**QV Wash**  
Cutaneous solution  
Glycerol

**ego**

**QV Wash**  
Cutaneous solution  
Glycerol

**Soap alternative for dry skin**

200 mL

**QV Wash**  
Cutaneous solution  
Glycerol

**Soap alternative for dry skin.**

Colour free     Lanolin free     pH 6  
 Perfume free     Propylene glycol free

**QV Wash** is a soap alternative for the treatment of dry, scaly skin in ichthyosis, xerosis, pruritus hiemalis, allergic dermatitis and sun-damaged skin. For the temporary relief of symptoms of atopic or infantile eczema and psoriasis. Suitable for infants and the elderly.

**DIRECTIONS:** For topical use only. Use as often as required in the shower or in the hand basin. Wet skin, apply a small amount and massage lightly into skin. Rinse and pat dry.

**CAUTION:** Avoid contact with eyes. If lather enters eyes, flush with clean water. Discontinue use if irritation occurs. See Product Information Leaflet for specific information regarding E216 and E218.

Keep out of reach and sight of children.  
Do not store above 25°C. Batch and expiry see base.

**ACTIVE INGREDIENT:** Glycerol 10% w/w

**ALSO CONTAINS:** citric acid anhydrous, disodium cocoamphodiacetate, ethylene glycol monopalmitostearate, lauryl betaine, PEG-120 methyl glucose dioleate, sodium cocoyl isethionate, sodium laurilsulfate, purified water, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216).

**Marketing Authorisation Holder:**  
Ego Pharmaceuticals (UK) Limited    74034  
15 Windsor Park, London, SW19 2TJ UK

**Distributed by:** Crawford Pharmaceuticals,  
Goostrey CW4 6JP

'Ego' and 'QV' are Trade Marks of  
Ego Pharmaceuticals Pty Ltd. (Australia).  
©Ego. PL18278/0004




The batch number and expiry date are printed on the base of the bottle, as stated on the label.

240 Millilitre Pack



The batch number and expiry date are printed on the base of the carton, as stated on the label.



130mm



The batch number and expiry date are printed on the base of the bottle, as stated on the label.

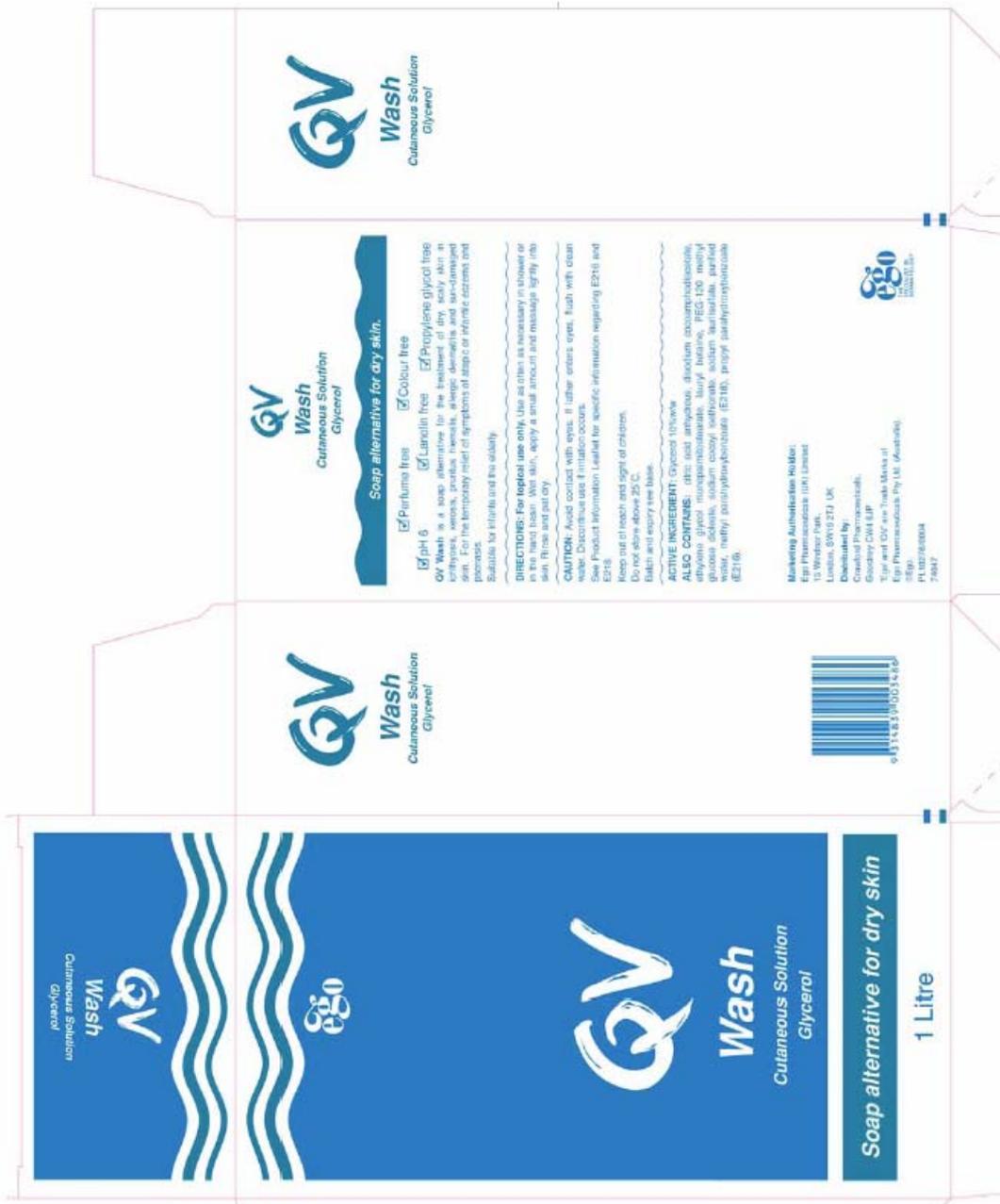
500 Millilitre Pack



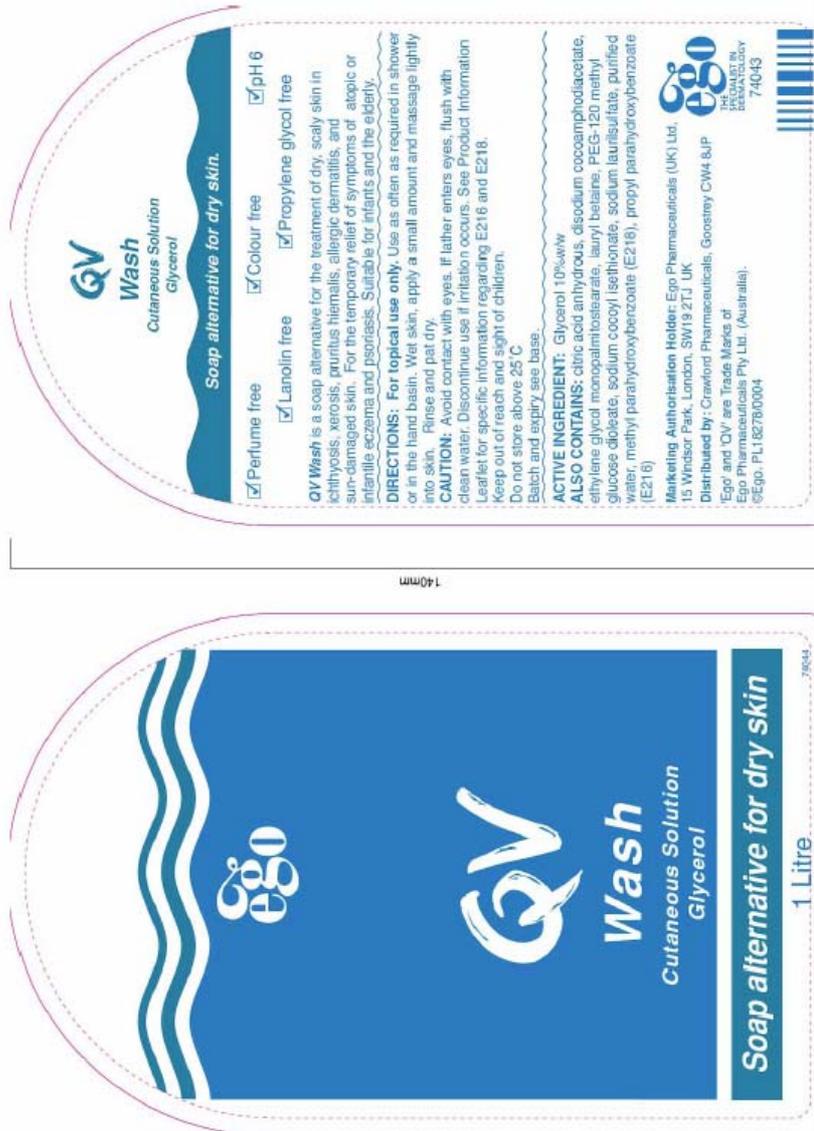
The batch number and expiry date are printed on the base of the bottle, as stated on the label.



1 Litre Pack



The batch number and expiry date are printed on the base of the carton, as stated on the label.



The batch number and expiry date are printed on the base of the bottle, as stated on the label.