PARTICULARS TO APPEAR ON LABEL

BASE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Aqueous Cream BP
(Hydrous Emulsifying Ointment)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

This preparation contains: White Soft Paraffin BP 15.0% w/w and Liquid Paraffin BP 6.0% w/w.

3. LIST OF EXCIPIENTS

Also includes: Emulsifying Wax BP, 2-Phenoxyethanol, Purified Water.

4. PHARMACEUTICAL FORM AND CONTENTS

Container:

500 g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

HOW TO USE IT

AGE	**DOSAGE**
ADULTS, ELDERLY & CHILDREN	Apply sparingly to the affected area as and when required. When used as a vehicle for other active ingredients, dosage is to be as indicated by the dispensing pharmacist.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the reach and sight of children.

If this product comes into contact with dressings and clothing the fabric can be easily ignited with a naked flame. You should keep away from fire when using this product.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

For external use only.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Not applicable

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Not applicable

12. MARKETING AUTHORISATION NUMBER(S)

PL 28444/0133

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Not applicable

15. INSTRUCTIONS ON USE

Used as an emollient to soothe and soften dry skin.

For the relief of minor skin irritations and as a vehicle for active ingredients to be applied to the skin.

Do not use this product after its ‘EXP’ date.

Please read the Package Leaflet before use on the reverse of this label.

16. INFORMATION IN BRAILLE

Aqueous Cream BP

PACKAGE LEAFLET: INFORMATION FOR THE USER

AQUEOUS CREAM BP
(HYDROUS EMULSIFYING OINTMENT)
(Paraffin Soft White and Paraffin Liquid)

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Aqueous Cream BP (Hydrous Emulsifying Ointment) carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Aqueous Cream is and what it is used for
2. Before you give Aqueous Cream
3. How to give Aqueous Cream
4. Possible side effects
5. How to store Aqueous Cream
6. Further information

1. WHAT AQUEOUS CREAM IS AND WHAT IT IS USED FOR

The name of your medicine is Aqueous Cream BP. It contains the active ingredient paraffin soft white and paraffin liquid.

It is used for the relief of minor skin irritations and as a vehicle for active ingredients to be applied to the skin.

2. BEFORE YOU USE AQUEOUS CREAM

Do not use Aqueous Cream if you are allergic (hypersensitive) to paraffin soft white and paraffin liquid or to any of the other ingredients. See section 6.

Take special care with Aqueous Cream
If this product comes into contact with dressings and clothing the fabric can be easily ignited with a naked flame. You should keep away from fire when using this product.

Taking other medicines

Please consult your pharmacist if you are taking or have taken recently taken any other medicines, including medicines obtained without prescription. Aqueous Cream may react other medicines and products.

Pregnancy and Breast-feeding

Aqueous Cream can be used during pregnancy and lactation. However, if you are pregnant, consult your doctor or pharmacist before use.

3. HOW TO USE AQUEOUS CREAM

Follow the directions on this package leaflet or pack carefully, and ask your pharmacist to explain any part you do not understand. For external use only.

Use as an emollient
For Adults, the Elderly and Children:
Apply sparingly to the affected area as and when required.

Use as vehicle for other active ingredients
Dosage as indicated by the dispensing pharmacist.

If you accidentally swallow Aqueous Cream or use more than you should
Please consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Aqueous Cream can cause side effects, although not everybody gets them.

Very serious side effects –if any of the following happens, **stop using** Aqueous Cream and tell your doctor immediately or go to the nearest hospital emergency department:

- Allergic (hypersensitivity) reactions

If any of the side-effects gets serious or if you notice any side-effect not listed here, please tell your doctor or pharmacist.

5. HOW TO STORE AQUEOUS CREAM

Keep out of the reach and sight of children.

Keep the container tightly closed. Do not store above 25°C.

Do not use Aqueous Cream after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Aqueous Cream should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of this product no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Aqueous Cream contains
The active ingredients are Paraffin Soft White BP 15.0% w/w and Paraffin Liquid BP 6.0% w/w. The other ingredients are 2-Phenoxyethanol and Emulsifying Wax.

What Aqueous Cream looks like and contents of the pack
Aqueous Cream is a homogenous white cream and comes in opaque container with lid in pack sizes of 30g or 500g. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Activase Pharmaceuticals Limited, 11 Boumpoulinas, 3rd Floor, P.C. 1060, Nicosia, Cyprus.

Manufacturer
GlobeGen Laboratories Ltd.,1406 Coventry Road, South Yardley, Birmingham, B25 8AE, UK.

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