

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Torbetol Acne Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrimide Ph. Eur.	0.7	% w/v
Chlorhexidine Gluconate Solution Ph. Eur.	0.75	% v/v

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cutaneous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

'Torbetol' Acne Lotion is recommended for the treatment of acne vulgaris.

4.2 Posology and method of administration

'Torbetol' Acne Lotion is for cutaneous use.

Adults and Children over 12 years of age:

Directions:

1. It is preferable to wash the affected areas thoroughly but gently in lukewarm water.
2. Apply 'Torbetol' Acne Lotion with cotton wool to affected area, allow to dry.
3. Repeat application.
4. The procedure should be followed thrice daily.

4.3 Contraindications

'Torbetol' Acne Lotion is for external use only. Contact with eyes, lips and mouth should be avoided.

Use in persons hypersensitive to any of the ingredients.

4.4 Special warnings and special precautions for use

If there is aggravation of the condition or no improvement, consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

Soaps decrease the activity of both chlorhexidine gluconate and cetrimide.

4.6 Pregnancy and lactation

The active constituents of 'Torbetol' Acne Lotion have been in wide use for many years without apparent ill consequence.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Rarely with prolonged application, skin sensitivity could occur and treatment should be discontinued.

Side-effects include local irritation and erythema.

4.9 Overdose

Accidental Ingestion:

Symptoms - Nausea and vomiting may occur.

Treatment - carry out stomach lavage with milk, egg white or mild soap. Treat symptoms symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

'Torbetol' Acne Lotion contains two active ingredients. Chlorhexidine Gluconate is a disinfectant which is effective against a wide range of vegetative Gram positive and negative bacteria. It is ineffective against acid fast bacteria, bacterial spores, fungi and viruses. It is more effective against Gram positive than Gram negative bacteria. Some species of Pseudomonas and Proteus are relatively less susceptible.

Cetrimide has properties and uses typical of cationic surfactants. It has bacterial activity against both Gram positive and negative organisms but is relatively ineffective against bacterial spores, acid fast bacteria, viruses and fungi.

5.2 Pharmacokinetic properties

The activity of 'Torbetol' Acne Lotion is not dependant on the percutaneous absorption of the two active ingredients.

5.3 Preclinical safety data

No remarks.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial Methylated Spirits Ph. Eur.

Patent blue (E131)

Purified water Ph. Eur.

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Clear, glass bottle with foil faced plastic screw cap containing 50 ml of product.

6.6 Instructions for use and handling

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Name and address of Marketing Authorisation Holder

Torbet Laboratories Limited
14D Wendover Road
Rackheath Industrial Estate
Norwich
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NR13 6LH
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8 MARKETING AUTHORISATION NUMBER

PA 456/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th June 1991

Date of last renewal: 10th June 2001

10 DATE OF REVISION OF THE TEXT

January 2002