

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0206/029/001

Case No: 2043901

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Ovelle Limited

Dundalk Industrial Estate, Coe's Road, Dundalk, Co. Louth, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Aidex First Aid Antiseptic Cream, Aminoacridine Hydrochloride 0.1% w/w, Benzocaine 0.1% w/w, Phenoxyethanol 1.0% w/w

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **11/02/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aidex First Aid Antiseptic Cream
Aminoacridine Hydrochloride 0.1% w/w,
Benzocaine 0.1% w/w,
Phenoxyethanol 1.0% w/w.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Aminoacridine Hydrochloride 0.1 % w/w,
Benzocaine 0.1 % w/w,
Phenoxyethanol 1.0 % w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A pale yellow cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Aidex Cream is a cream for the symptomatic treatment of minor abrasions and scalds.

4.2 Posology and method of administration

Aidex Cream is applied topically and is for external use only.

4.3 Contraindications

Aidex Cream is contra-indicated in patients with a known sensitivity to its ingredients.

4.4 Special warnings and precautions for use

No adverse effects reported.

4.5 Interaction with other medicinal products and other forms of interaction

No adverse effects reported.

4.6 Pregnancy and lactation

No adverse effects reported.

4.7 Effects on ability to drive and use machines

No adverse effects reported.

4.8 Undesirable effects

None reported.

4.9 Overdose

No special procedures or antidote is likely to be necessary. In case of over use, wash off with soap and hot water.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Aminacrine Hydrochloride,

Aminacrine Hydrochloride (an acridine derivative) is non-staining and is used for the treatment of wounds, burns and for skin disinfection.

Benzocaine,

Benzocaine is a surface anaesthetic of the ester type with low systemic toxicity.

5.2 Pharmacokinetic properties

Benzocaine,

Benzocaine is readily released from oil in water bases. Most local anaesthetics are readily absorbed through mucous membranes and through damaged skin. Local anaesthetics are weak bases and at tissue pH can diffuse through connective tissue and cellular membranes to reach the nerve fibre where isolation can occur.

Anaesthetics of the ester type are hydrolysed by esterases in the plasma and to a lesser extent in the liver.

5.3 Preclinical safety data

No further information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying wax,
Paraffin, soft yellow,
Glycerol,
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

Keep container tightly closed.

Keep container in the outer carton.

6.5 Nature and contents of container

30 g aluminium tube with polyethylene screw cap. Each tube is packed in cardboard carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Ovelle Ltd.,
Dundalk Industrial Estate,
Coe's Rd,
Dundalk,
Co. Louth.
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 206/29/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th February 1993

Date of last renewal: 11th February 2008

10 DATE OF REVISION OF THE TEXT

April 2008.