



SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. NAME OF THE MEDICINAL PRODUCT

Aserbine Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Malic Acid 0.375g
 Benzolic Acid Ph. Eur. 0.025g
 Salicylic Acid Ph. Eur. 0.006g
 Propylene Glycol 1.75ml Ph.Eur per 100g marketed pack.

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Whenever the presence of slough delays healing:
 Chronic skin ulcers;
 Venous (varicose) ulcers and other benign chronic ulcers; trophic
 Ulcers including pressure sores.

 Burms.
 Traumatic injuries;
 Crushed limb injuries; multiple lesions.
 Surgical procedures where slough may be a problem;
 Preparation for skin grafting; mastectomies, amputation., post-surgical incisions.
2. Cleaning:
 Wounds and abrasions where coagulum, debris, dirt and grit etc. are a problem.

4.2 Posology and method of administration

Method of administration

Aserbine solution should be applied topically.

Dosage:

Aserbine cream is suitable for both adults (including elderly) and children.

Dressing the wound twice daily has been found to produce the best results; however, more frequent dressings may be made if necessary. "Aserbine" cream should be applied liberally to the wound surface and before each new application the wound should be washed with "Aserbine" solution so that the loose slough and cream from the previous application are removed.

4.3 Contraindications

None

4.4 Special warnings and special precautions for use

"Aserbine" is for external use only. Care should be taken to avoid contact with the eyes because of "Aserbines" low pH.

4.5 Interactions with other medicinal products and other forms of interaction

No specific information available.

4.6 Pregnancy and lactation

"Aserbine" has been in clinical use since 1965. However, there is no documented experience of its use in human pregnancy or lactation. As with all medicines, careful consideration should be given before the use of "Aserbine" during the first trimester.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Mild pyrexia, partially due to the absorption of protein products of slough breakdown from the wound, has been reported in severely burned patients. Irritation of the hypersensitive skin surrounding the wound may occur in a few patients. In these cases, "Aserbine" should be kept away from the growing epithellum at the periphery of the wound.

Occasionally a mild urticarial rash has been seen a small distance around the treated area, the discomfort was slight and readily controlled by antihistamines.

4.9 Overdose

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not Applicable

5.2 Pharmacokinetic properties

Not Applicable

5.3 Preclinical safety data

No further information.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin BP
Sorbitan sesquioleate
Cholesterol BP
Magnesium Sulphate Ph. Eur.
Allantoin
Methyl Parahydroxybenzoate Ph. Eur.
Propyl Parahydroxybenzoate Ph Eur.
Purified Water PhEur.

6.2 Incompatibilities

None.

6.3 Shelf life

3 years when stored in a cool place.

6.4 Special precautions for storage

Store in a cool place.

6.5 Nature and contents of container

Internally lacquered printed aluminium blind end tube fitted with a threaded nozzle. The cap is polyethylene and externally spiked.

Pack size: 100g

6.6 Instructions for use/handling

None.

Administration Details

7. MARKETING AUTHORISATION HOLDER

Forley Ltd	T/A Forley Road
Registered Office	4 Priory Hall
20 Clanwilliam Terrace	Stillorgan Road
Dublin 2	Co Dublin

8. MARKETING AUTHORISATION NUMBER

PL 12300/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th February 1994

10. DATE OF (PARTIAL) REVISION OF TEXT

November 1998