



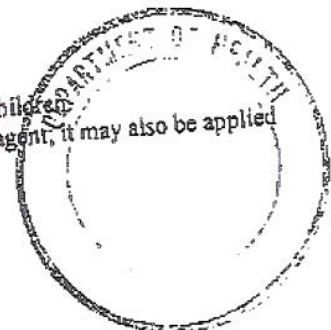
## SUMMARY OF PRODUCT CHARACTERISTICS

### Product Summary

1. **Name of the Medicinal Product**  
Aserbine solution
2. **Qualitative and Quantitative Composition**  
Malic Acid 2.25g  
Benzoic Acid Ph. Eur. 0.15g  
Salicylic Acid Ph. Eur. 0.0375g  
Propylene Glycol 40ml Ph.Eur per 500ml marketed bottle.
3. **Pharmaceutical Form**  
Solution

### 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.  
Burns.  
Traumatic injuries;  
Crushed limb injuries; multiple lesions.  
Surgical procedures where slough may be a problem;  
Preparation for skin grafting; mastectomies, amputations, 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.  
Aserbine solution is suitable for both adults (including elderly) and children.  
"Aserbine" solution should be used undiluted as a general cleansing agent, it may also be applied as a wet dressing.
- 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 "Aserbine's" low pH. Prolonged contact of "Aserbine" solution with metallic surfaces is inadvisable.

**4.5 Interactions with other Medicaments 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 epithelium 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

**Pharmacological Properties**

Pharmacodynamic Properties

Not Applicable.

Pharmacokinetic Properties

Not Applicable.

Preclinical Safety Data

Not Applicable.

Other Particulars



6.1 List of Excipients

Oil of Rose  
Alcohol 96%  
Purified Water

6.2 Incompatibilities

None.

6.3 Shelf Life

24 months.

6.4 Special Precautions for Storage

Store in a cool place.

6.5 Nature and Contents of Container

Polypropylene bottle with plug insert and polyethylene cap.  
Pack size: 500ml

6.6 Instructions for Use/Handling

None.

Administrative Data

7. Marketing Authorisation Holder

Forley Limited  
Registered Office  
20 Clanwilliam Terrace  
Dublin 2

T/A Forley Ltd  
4 Priory Hall  
Stillorgan Road  
Co Dublin

Marketing Authorisation Number

PL 12300/0002

Date of First Authorisation/Renewal of the Authorisation

28 February 1994

Date of (Partial) Revision of Text

November 98