

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Actal 360mg Orodispersible Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Alexitol Sodium 360mg.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Orodispersible Tablet

A round, flat bevel-edged tablet with 'Actal' embossed on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antacid.

4.2 Posology and method of administration

Actal tablets are for oral administration only.

Adults and Elderly: Two tablets to be dissolved on the tongue up to 8 times per day. The dose may be repeated as required. Do not take more than 16 tablets in 24 hours.

Children: Not suitable for children under 12 years of age.

4.3 Contraindications

There are no known contraindications.

4.4 Special warnings and precautions for use

If symptoms persist, consult your doctor. Keep out of the reach of children.

Aluminium hydroxide may cause constipation due to its astringent action.

Aluminium hydroxide may lead to a phosphate depletion syndrome, particularly in patients on a low phosphate diet e.g. malnutrition.

4.5 Interaction with other medicinal products and other forms of interaction

Antacids may reduce the absorption of other drugs, including tetracyclines, digoxin and vitamins.

4.6 Pregnancy and lactation

There is inadequate evidence of safety of Actal in human pregnancy, but it has been in wide use for many years without apparent ill consequence. However, careful consideration should be given before treating pregnant patients with Actal, particularly during the first trimester.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

No statement.

4.9 Overdose

There have been no cases of overdose stated. If a large amount is taken, it should be sufficient to empty the stomach by emesis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code}

Actal compares well with liquid aluminium hydroxide gel in rate and amount of acid neutralised, and in maintenance of the pH at the optimum range of 3.5 to 4.5. In particular, the superiority of Actal over dried aluminium hydroxide gels is apparent: the loss of activity that may accompany drying and tableting of these gels is well known and results are available to show that Actal is at least twice as rapid in action as the best dried gel.

5.2 Pharmacokinetic properties

Alexitol sodium, the active constituent in Actal Tablets, is not absorbed. There are, therefore, no pharmacokinetic data.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Mannitol (E421)
Talc
Magnesium stearate
Saccharin sodium
Peppermint oil

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

5 years

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

PVC/aluminium foil blister packs in outer cardboard box: 12, 24, 48 or 96 tablets.

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

Seven Seas Limited
T/A Merck Consumer Health
Hedon Road
Marfleet
Kingston-Upon-Hull
HU9 5NJ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA0417/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2003

10 DATE OF REVISION OF THE TEXT

August 2005