

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Endekay Disclosing Tablets Erythrosine 6mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Erythrosine 6 mg

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an aid to the teaching of efficient oral hygiene.

4.2 Posology and method of administration

The patient should be given a tablet in the surgery. This will at once demonstrate the shortcomings of the patients' oral hygiene techniques and make it easier to gain co-operation

When the correct method of brushing teeth has been shown, send the patient home with a supply of the tablets and instructions on how to use them. Endekay Disclosing Tablets Erythrosine 6 mg will play a central role in helping the patient to acquire the habit of regular and correct tooth brushing.

Initially use once a day. The patient should crush one tablet between the teeth before cleaning them, and distribute the saliva to all tooth and gum surfaces with the aid of the tongue for at least half a minute. The patient should then spit into a bowl of running water, and rinse the mouth out once or twice with water.

The patient should then brush the teeth as shown until all the red stain has been removed. Once a sound brushing technique has been established the patient can use Endekay Disclosing Tablets Erythrosine 6 mg from time to time after brushing, as a check to proficiency.

In the same way, patients should be given Endekay Disclosing Tablets Erythrosine 6 mg from time to time on visits to the surgery to assess their progress.

Oral as a mouthwash

4.3 Contraindications

Hypersensitivity to erythrosine or any of the other ingredients

4.4 Special warnings and precautions for use

None reported.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

Endekay Disclosing Tablets Erythrosine 6 mg is not contraindicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Gastric lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Erythrosine is a dye consisting principally of the monohydrate of 2',4', 5', 7'-tetraiodofluorescein disodium salt, with smaller amounts of lower iodinated fluoresceins. It is used in Endekay Disclosing Tablets Erythrosine 6 mg to stain dental plaque and food debris to a brilliant red, and thus to help in the establishment of good oral hygiene.

5.2 Pharmacokinetic properties

The tablet is chewed to release the dye but is not swallowed. The contents of the mouth after chewing are spat out and the mouth rinsed. There is therefore minimal or no absorption.

5.3 Preclinical safety data

None

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol, pregelatinised starch, saccharin sodium, menthol, thymol, magnesium stearate, eucalyptus oil.

6.2 Incompatibilities

None.

6.3 Shelf life

Five (5) years.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Blister packs of 12, 14 and 240 tablets.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Tillomed Laboratories Limited

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Luton

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8 MARKETING AUTHORISATION NUMBER(S)

PL 11311/0782

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

1 September 1997/23 February 2009

10 DATE OF REVISION OF THE TEXT

27/06/2025