PROFESSIONAL INFORMATION

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1 NAME OF THE MEDICINE

OXY-5 LOTION

OXY-10 LOTION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g OXY-5 LOTION contains Hydrous benzoyl peroxide equivalent to 5,0 g benzoyl peroxide. Preserved with Propyl hydroxybenzoate 0,05 % *m/m* and Methyl hydroxybenzoate 0,15 % *m/m*.

Each 100 g OXY-10 LOTION contains Hydrous benzoyl peroxide equivalent to 10,0 g benzoyl peroxide. Preserved with Propyl hydroxybenzoate 0,05 % *m/m* and Methyl hydroxybenzoate 0,15 % *m/m*.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

OXY LOTION is a smooth white lotion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

OXY-5 and OXY-10 lotions are indicated for the treatment of moderate acne-vulgaris (pimples and blackheads).

4.2 Posology and method of administration

1. Shake container well before use.
2. Apply to affected area once a day. Rub in well. Avoid contact with eyes, lips and mouth.
3. Leave on your skin for only 2 hours before washing it off with water. Continue for 2 to 4 days.
4. If no discomfort is experienced, apply the lotion once daily and leave on for 4 hours before washing off with water. Continue for the next 4 days.
5. Then, apply at night and leave on overnight for the next week.
6. Then apply morning and night.

If excessive drying of the skin occurs, reduce to 1 application daily and gradually increase application to two or three times daily as needed.

If the condition has not improved within 14 days, consult your doctor or pharmacist.

4.3 Contraindications

Concomitant use with isotretinoin.

Patients who are hypersensitive to benzoyl peroxide.

4.4 Special warnings and precautions for use

If the condition has not improved within 14 days, consult your doctor or pharmacist.

If you are unsure or have not used this product before, test it, at least 24 hours before using it, by applying some product to a small area of the lower arm. If there is a severe redness or irritation, do not use the product.

Apply with caution to the neck as the skin of this area is very sensitive to medication.

OXY-5 and OXY-10 may bleach clothing, bed linen, eyebrows and hair.

If burning, redness or excessive peeling occur, discontinue the medication until the irritation subsides, then resume treatment at former level. If it persists seek medical advice.

If excessive drying of the skin occurs, reduce to one application daily then gradually increase to two or three times daily as needed.

FOR EXTERNAL USE ONLY.

4.5 Interaction with other medicines and other forms of interaction

A cumulative irritant or drying effect, especially with the application of peeling, desquamating or abrasive agents, resulting in excessive irritation of the skin may result with the concurrent use of OXY-5 and OXY-10 with the following:

- Abrasive or medicated soaps or cleansers.
- Acne preparations or preparations containing a peeling agent such as resorcinol, salicylic acid, sulphur or tretinoin.
- Topical, alcohol containing preparations such as after-shave lotions, astringents, perfumed toiletries, shaving creams or lotions or cosmetics or soaps with strong drying effects.
- Isotretinoin
- Medicated cosmetics or “cover-ups”.

The concurrent use of OXY-5 and OXY-10 with tretinoin may inactivate the tretinoin.

4.6 Fertility, pregnancy and lactation

This medication may be systemically absorbed. The safety of this preparation in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Skin and subcutaneous tissues disorders

Frequently observed

When first applied, a mild burning sensation is usually felt. Moderate erythema (redness of the skin) and desquamation appear within a few days. At some time during the first month of treatment, a sudden increased peeling of the skin will occur in most patients. This is not harmful and subsides within a day or two if treatment is temporarily discontinued. This seldom recurs, but should this be the case, application for a shorter period each day may enable continuation of treatment.

Less frequently

Dryness or peeling of the skin (may occur after a few days)

Feeling of warmth

Mild stinging or redness of the skin

Less frequently or rare

Allergic contact dermatitis (burning, blistering, crusting, itching, severe redness or swelling of the skin)

Irritant effect (painful irritation of the skin)

Skin rash

The following side effects have been reported - frequency unknown

Transient local oedema

Contact sensitisation

Perioral (skin around the mouth) tightness and fissuring

Others:

Contact allergic sensitivity to OXY-5 and OXY-10 appear more likely in patients with fair sensitive skin and can be minimised by avoiding the use of benzoyl peroxide. Allergic reactions are readily suppressed with systemic antihistamines or with systemic and local corticosteroid therapy.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

There are no known cases of over-dosage with this type of product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.11 Acne preparations

Hydrous benzoyl peroxide exhibits keratolytic (ability to soften or remove dead skin), antiseborrhoeic (suppresses over production of fatty oil secretion of the skin), anti-bacterial (destroys or suppresses the growth or production of bacteria including *Propionibacterium Acnes (p. acnes))* and comedolytic properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol,

colloidal silicon dioxide,

propylene glycol,

self-emulsifying glyceryl monostearate,

sodium lauryl sulfate,

citric acid anhydrous,

sodium citrate dehydrate and

purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

OXY-5 and OXY-10 is presented in 15 g, 25 g and 40 g tubes.

6.6 Special precautions for disposal

None.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Mentholatum South Africa (Pty) Ltd

1st Floor, Silverberg Terrace

Steenberg Office Park

Silverwood Close

Tokai

7945

8 REGISTRATION NUMBER

OXY-5 Lotion: N/13.12/104

OXY-10 Lotion: N/13.12/112

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

10 August 2007

10 DATE OF REVISION OF THE TEXT

24 August 2022