PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

OXY-5 LOTION, 5 g/100 g lotion

OXY-10 LOTION, 10 g/100 g lotion

The active substance per 100 g lotion is hydrous benzoyl peroxide equivalent to 5 g benzoyl peroxide (5 % *m/m*) for OXY-5 and equivalent to 10 g benzoyl peroxide (10 % *m/m*) for OXY-10.

Read all of this leaflet carefully because it contains important information for you

OXY-5 and OXY-10 are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use OXY-5 and OXY-10 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OXY-5 and OXY-10 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What OXY-5 and OXY-10 is and what it is used for
2. What you need to know before you use OXY-5 and OXY-10
3. How to use OXY-5 and OXY-10

4. Possible side effects
5. How to store OXY-5 and OXY-10
6. Contents of the pack and other information

1 What OXY-5 and OXY-10 are and what it is used for

OXY-5 and OXY-10 are used for the treatment of moderate pimples and blackheads.

2 What you need to know before you use OXY-5 and OXY-10

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

OXY-5 and OXY-10 are for external use only.

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

Do not use OXY-5 and OXY-10:

- if you are hypersensitive (allergic) to benzoyl peroxide or any of the other ingredients in OXY-5 and OXY-10 (listed in section 6).
- together with any other product that contains isotretinoin (another drug used for acne) as it may inactivate the tretinoin.

Warnings and precautions

Take special care with OXY-5 and OXY-10:

- when you apply OXY-5 and OXY-10 to the neck as the skin of this area is very sensitive to medication.
- when you use OXY-5 and OXY-10 together with:

- abrasive or medicated soaps or cleansers
- other acne preparations or preparations with a peeling agent such as resorcinol, salicylic acid or sulphur
- topical alcohol containing products such as after-shave lotions, astringents, perfumed toiletries, shaving creams or lotions or cosmetics or soaps with strong drying effects
- medicated cosmetics or “cover-ups”
- peeling, desquamating or abrasive agents

If you use OXY-5 and OXY-10 with any of these products, it may cause an additional irritant or drying effect. This can result in excessive irritation of the skin.

If you have a fair skin you are more likely to experience contact allergic sensitivity. You should minimise the use of OXY-5 and OXY-10.

Other medicines and OXY-5 and OXY-10

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Pregnancy and breastfeeding

This medication may be systemically absorbed.

The safety of OXY-5 and OXY-10 in pregnant and breastfeeding women has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines

OXY-5 and OXY-10 should not have any effect on your ability to drive or to use machines.

3 How to use OXY-5 and OXY-10

Do not share medicines prescribed for you with any other person.

Always use OXY-5 and OXY-10 exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Shake container well before use.
OXY-5 and OXY-10 should be applied to the affected area once a day for 2 to 4 days. Rub in well and leave for only 2 hours. Then remove with water.
Avoid contact with eyes, lips and mouth.
If no discomfort is experienced, apply the lotion once a day for the next 4 days and leave for 4 hours before washing off.
Then apply at night for one week and leave on overnight.
Then apply morning and night.

If excessive drying of the skin occurs, reduce to one application per day the gradually increase to two or three times a day as needed.
If the condition has not improved within 14 days, consult your doctor or pharmacist.

If you use more OXY-5 and OXY-10 than you should

There are no known cases of overdosage with this type of product.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4 Possible side effects

OXY-5 and OXY-10 can have side effects.

A mild burning sensation is usually felt on first application and a slightly red skin rash and flaking of the skin appears within a few days. At some time during the first month of treatment, sudden increased peeling of the skin will occur in most patients. This is not harmful and goes away within a day or two if treatment is temporarily stopped. If this happens, application for a shorter period each day may allow you to continue treatment.

Dryness or peeling of the skin may occur after a few days. Also a feeling of warmth or a mild stinging or redness of the skin.

An increased peeling of the skin will subside within a day or two if you stop using the lotion temporarily. If you apply the lotion for a shorter period of time every day, you should be able to continue with the treatment.

Allergic reactions may occur such as burning, blistering, crusting, itching, severe redness or swelling of the skin. A painful irritation of the skin or skin rash may occur.

You could also experience temporary local fluid retention or contact allergic sensitivity or tightness and cracking of the skin around the mouth.

If burning, redness or excessive peeling of the skin occur, stop using the medication until the irritation subsides. Then carry on again the same as before. If these conditions persist, consult your doctor.

Not all side effects reported for OXY-5 and OXY-10 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using OXY-5 and OXY-10, please consult your health care provider for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OXY-5 and OXY-10. You may also report side effects directly to https://www.mentholatum.co.za

5 How to store OXY-5 and OXY-10

Store all medicines out of reach of children.

Store at or below 25 ºC.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Content of the pack and other information

What OXY-5 and OXY-10 contains

- The active substance per 100 g OXY-5 is hydrous benzoyl peroxide equivalent to 5 g benzoyl peroxide (5 % *m/m*) and
- the active substance per 100 g OXY-10 is hydrous benzoyl peroxide equivalent to 10 g benzoyl peroxide (10 % *m/m*).
- The other ingredients are cetyl alcohol, citric acid, colloidal silicon dioxide, propylene glycol, self-emulsifying glyceryl monostearate, sodium citrate, sodium lauryl sulphate and purified water.
- OXY-5 and OXY-10 are preserved with:
    - Propyl hydroxybenzoate 0,05 % *m/m* and
    - Methyl hydroxybenzoate 0,15 % *m/m*

What OXY-5 and OXY-10 looks like and contents of the pack

OXY-5 and OXY-10 are a smooth, white lotion.

OXY-5 and OXY-10 are presented in plastic tubes containing 15 g, 25 g and 40 g lotion.

Holder of Certificate of Registration

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This leaflet was last revised in

24 August 2022

Registration number

Oxy-5 Lotion: N/13.12/104

Oxy-10 Lotion: N/13.12/112

Access to the corresponding Professional Information

The PI can be found online under Mentholatum SA's website:

https://www.mentholatum.co.za/product-information/.