PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 0

PROPRIETARY NAME AND DOSAGE FORM:

BENZAC AC 5 GEL

Benzoyl peroxide 5 g per 100 g gel

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

BENZAC AC 5 GEL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use BENZAC AC 5 GEL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BENZAC AC 5 GEL with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

1. WHAT BENZAC AC 5 GEL CONTAINS

The active substance is benzoyl peroxide.

The other ingredients are acrylates copolymer, carbomer 940, disodium edetate, glycerol, poloxamer 182, propylene glycol, silica colloidal anhydrous, sodium dioctyl sulphosuccinate, sodium hydroxide (10 %) solution and water.

2. WHAT BENZAC AC 5 GEL IS USED FOR

- BENZAC AC 5 GEL is used for the topical treatment of *acne vulgaris*. BENZAC AC 5 GEL contains the active ingredient benzoyl peroxide which attacks the bacteria (germs) known as propionibacterium acnes, one of the main causes of acne.
- Your doctor or pharmacist has recommended this medicine to treat your acne. Acne appears as blackheads and whiteheads which people often refer to as pimples or spots.

3. BEFORE YOU USE BENZAC AC 5 GEL

Do not use BENZAC AC 5 GEL:

- If you are hypersensitive (allergic) to benzoyl peroxide or any of the other ingredients of BENZAC AC 5 GEL (see section 1 for other ingredients). An allergic reaction may include a rash or itching.

Take special care with BENZAC AC 5 GEL:

- Avoid contact with the eyes, mouth, angles of the nose and other mucous surfaces such as the lining of your nose. If accidental contact should occur, rinse thoroughly with warm water.
- BENZAC AC 5 GEL should not be applied to damaged skin.
- This product may bleach hair and coloured fabrics including clothing, towels and bed linen. Be careful to avoid contact of the gel with these materials. Please make sure that you wash your hands thoroughly after you have used it.
- Avoid excessive exposure to sunlight or UV lamps.

Pregnancy and breastfeeding:

Pregnancy

If you are pregnant or think you may be pregnant or are breastfeeding, do not use BENZAC AC 5 GEL.

Breastfeeding

Avoid using BENZAC AC 5 GEL if you are breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using BENZAC AC 5 GEL.

Using other medicines with BENZAC AC 5 GEL:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

4. HOW TO USE BENZAC AC 5 GEL

- BENZAC AC 5 GEL is FOR EXTERNAL USE ONLY.
- Unless your doctor or pharmacist has told you otherwise,
    - Wash the affected area with a mild skin cleanser and water, and gently pat your skin dry.
    - Apply the gel once or twice a day to all the affected areas.
    - Any drying or peeling which may occur to your skin may be reduced if you change the number of applications, i.e. apply once a day or once every two days, until your skin adjusts to the product.
- You should try to avoid exposure to strong sunlight while using BENZAC AC 5 GEL. If exposure is unavoidable, use a suitable sunscreen lotion and apply BENZAC AC 5 GEL in the evening. Remember to wash the affected area before use.
- How long you will have to use BENZAC AC 5 GEL will depend on how quickly your condition improves. After you have used it for one month, you should see your doctor or pharmacist again. He or she can then check the improvement of your condition.

If you use more BENZAC AC 5 GEL than you should:

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

- If you should accidentally use too much gel, you may find that your skin becomes irritated. Wash off as much as you can, and when the irritation has gone down, start using it again as directed.
- In the rare event that you accidentally swallow any of this product, consult your doctor or pharmacist. If neither is available seek help at the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS

BENZAC AC 5 GEL can have side effects.

- If your skin becomes severely irritated, or severe redness, itching or peeling of the skin occurs, or you experience face swelling, discontinue use immediately and consult your doctor or pharmacist.
- It is normal in the first weeks to experience a feeling of skin tension, dryness or a burning, stinging or itching sensation, and a small amount of peeling or reddening of the skin. These effects are usually mild and will go when treatment stops or the gel is applied less often.

Not all side effects reported for BENZAC AC 5 GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BENZAC AC 5 GEL, please consult your doctor, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF BENZAC AC 5 GEL

Store all medicines out of reach of children.

Do not use after the expiry date stated on the tube and carton. The expiry date refers to the last day of that month.

Store at or below 25 °C.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF BENZAC AC 5 GEL

BENZAC AC 5 GEL is available in plastic tubes containing 15 gram, 20 gram or 40 gram gel.

8. IDENTIFICATION OF BENZAC AC 5 GEL

White to slightly off-white, smooth and homogenous gel, without foreign particles with a characteristic odour.

9. REGISTRATION NUMBER / REFERENCE NUMBER

X/13.12/133

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

11. DATE OF PUBLICATION

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