Applicant:	**GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD**
Proprietary name:	**BENZAC® AC 5 GEL**
Registration Number	**X/13.12/133**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

BENZAC® AC 5 GEL

Benzoyl peroxide 5 g per 100 g gel

Read all of this leaflet carefully before you start using BENZAC® AC 5 GEL.

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- Do not share BENZAC® AC 5 GEL with any other person
- You must see a doctor if your symptoms worsen or do not improve

What is in this leaflet

1. What BENZAC® AC 5 GEL is and what it is used for

2. What you need to know before you start using BENZAC® AC 5 GEL

3. How BENZAC® AC 5 GEL is used

4. Possible side effects

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6. Contents of the pack and other information

1. What BENZAC® AC 5 GEL is and what it is used for

BENZAC® AC 5 GEL is a dermatological preparation.

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.

2. What you need to know before you use BENZAC® AC 5 GEL

Always tell your health care provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before using this medicine.

Do not use BENZAC® AC 5 GEL

- If you are allergic (hypersensitive) to benzoyl peroxide or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash or itching.

Warnings and precautions

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 (see section 4.6)
- Breastfeeding (see section 4.6)

Children

Do not use BENZAC AC® 5 GEL in children.

Other medicines and BENZAC AC® 5 GEL

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

Pregnancy and 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.

Pregnancy

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

Breastfeeding

Avoid using BENZAC® AC 5 GEL if you are breastfeeding.

Driving and using machines:

BENZAC® AC 5 GEL should not affect your ability to drive or use machines.

BENZAC® AC 5 GEL contains:

Propylene glycol that can be irritating to the skin.

3. How BENZAC® AC 5 GEL is used

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

Always use BENZAC® AC 5 GEL exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

BENZAC® AC 5 GEL IS FOR EXTERNAL USE ONLY

Unless your doctor or pharmacist has told you otherwise,

- Wash the affected area and gently pat your skin dry.
- Apply the gel once or twice a day to all the affected areas.
- If you have sensitive skin apply the gel once daily before going to bed.
- 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

BENZAC® AC 5 GEL is not to be taken by mouth and is for use on the skin only.

If, in the rare event that BENZAC® AC 5 GEL is accidentally swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison 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.

4. Possible side effects

BENZAC® AC 5 GEL can have side effects.

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 taking this BENZAC® AC 5 GEL, please consult your doctor, pharmacist or other healthcare professional for advice.

- 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 away when treatment stops, or the gel is applied less often.
- BENZAC® AC 5 GEL may cause swelling and blistering of the skin. If any of these symptoms occur, BENZAC® AC 5 GEL should be discontinued

BENZAC® AC 5 GEL may cause the following side effects:

Frequent side-effects:

- Dry skin
- Skin redness
- Peeling of the skin
- Burning sensation of the skin
- Itching of the skin (pruritis)
- Pain of the skin (pain, stinging)
- Skin irritation (irritant contact dermatitis)

Less frequent side-effects:

- Allergic contact dermatitis rash

Frequency unknown side-effects:

- Swelling face
- Allergic reactions, including application site hypersensitivity and anaphylaxis

These symptoms are usually reversible if the treatment is reduced in frequency or discontinued.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store BENZAC® AC 5 GEL

Store all medicines out of reach of children.

Do not use BENZAC® AC 5 GEL 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

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.

What BENZAC® AC 5 GEL looks like and contents of the pack

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

Pack contains:

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

Holder of Certificate of Registration:

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