Applicant:	**GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD.**
Proprietary name:	**BENZAC® AC 5 WASH**
Registration Number	**30/13.12/0044**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

BENZAC® AC 5 WASH

Benzoyl peroxide 5 g per 100 g wash

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

- 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 WASH with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 30 days

What is in this leaflet

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

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

3. How to use BENZAC® AC 5 WASH

4. Possible side effects

5. How to store BENZAC® AC 5 WASH

6. Contents of the pack and other information

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

BENZAC® AC 5 WASH is a dermatological preparation.

BENZAC® AC 5 WASH is used for the topical treatment of acne vulgaris.

BENZAC® AC 5 WASH 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 BENZAC® AC 5 WASH 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 WASH

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 WASH

- if you are hypersensitive (allergic) to benzoyl peroxide or any of the other ingredients of BENZAC® AC 5 WASH (listed in section 6).

Warnings and precautions

Take special care with BENZAC® AC 5 WASH:

- 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 WASH 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.

Children

Do not use BENZAC® AC 5 WASH in children.

Other medicines and BENZAC AC® 5 WASH

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

There is limited data on the use of topical benzoyl peroxide in pregnant women. If you are pregnant, 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

Breastfeeding

Avoid using BENZAC® AC 5 WASH if you are breastfeeding your infant.

You must not apply the wash onto your chest, in order to avoid exposure of your child to BENZAC® AC 5 WASH.

Driving and using machines:

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

3. How to use BENZAC® AC 5 WASH

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

Always use BENZAC® AC 5 WASH 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 WASH IS FOR EXTERNAL USE ONLY.

Unless your doctor or pharmacist has told you otherwise,

- Apply the wash once or twice a day to all the affected areas, whilst avoiding contact with your eyes, eyelids, mouth, angles of the nose and other mucous surfaces such as the lining of your nose.
- Rub in gently with your fingertips and leave on your skin for 30 seconds.
- Rinse off with water.
- Pat dry.
- 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 WASH. If exposure is unavoidable, use a suitable sunscreen lotion and apply BENZAC® AC 5 WASH in the evening. Remember to wash the affected area before use.
- How long you will have to use BENZAC® AC 5 WASH 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 WASH than you should

If, in the rare event that BENZAC® AC 5 WASH 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 wash, 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 WASH can have side effects.

Not all side effects reported for BENZAC® AC 5 WASH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this BENZAC® AC 5 WASH, 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 expected in the first weeks that you may feel skin tension, dryness or a burning, stinging or itching sensation, and experience 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 WASH may cause swelling and blistering of the skin. If any of these symptoms occur, BENZAC® AC 5 WASH should be discontinued

BENZAC® AC 5 WASH 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

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. 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 BENZAC® AC 5 WASH.

5. How to store BENZAC® AC 5 WASH

Store all medicines out of reach of children.

Do not use BENZAC® AC 5 WASH after the expiry date which is stated on the tube and the 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 WASH contains:

The active substance is benzoyl peroxide.

The other ingredients are:

carbomer 940, sodium C14 - C16 olefin sulphonate, sodium hydroxide (10 %) solution, glycerol, acrylates copolymer and water.

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

White to off-white smooth gel with a faint odour.

Pack contains:

BENZAC® AC 5 WASH is available in plastic tubes containing 100 gram wash.

Holder of Certificate of registration:

Galderma Laboratories South Africa (Pty) Ltd

Nicol Main Office Park,

Block C, First Floor,

FutureSpace,

2 Bruton Road, Bryanston,

2191

This leaflet was last revised in

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