Applicant: **Teva Pharmaceuticals (Pty) Ltd**
Product Name: FENACRATE 30 g / 50 g / 60 g / 100 g / 120 g / 150 g
Dosage form & strength: Each 1 g of gel contains 11,6 mg diclofenac diethylamine equivalent to 10 mg diclofenac sodium
Registration Numbers: 56/3.1/0373; 56/3.1/0374; 56/3.1/0375; 56/3.1/0376; 56/3.1/0377; 56/3.1/0378

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S0 FENACRATE 30 g, 50 g

S1 FENACRATE 60 g, 100 g, 120 g, 150 g

FENACRATE 30 g

FENACRATE 50 g

FENACRATE 60 g

FENACRATE 100 g

FENACRATE 120 g

FENACRATE 150 g

Diclofenac sodium (as diclofenac diethylamine)

Excipient(s) with known effect:

1 g of gel contains 50 mg/g propylene glycol (E1520) and 1 mg fragrance contains 0,15 mg/g benzyl alcohol, citral, citronellol, coumarin, eugenol, farsenol, geranoil, d-limonene and linalool (see **section 2** and **6**).

Read all of this leaflet carefully before you start using FENACRATE:

FENACRATE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FENACRATE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FENACRATE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT IS IN THIS LEAFLET:

1. WHAT FENACRATE IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FENACRATE

3. HOW TO USE FENACRATE

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE FENACRATE

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT FENACRATE IS AND WHAT IT IS USED FOR:

FENACRATE contains the active substance diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

FENACRATE is used to reduce inflammation and pain.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FENACRATE:

Do not use FENACRATE:

- if you are hypersensitive (allergic) to diclofenac, aspirin, other non-steroidal anti-inflammatory medicines or any of the other ingredients of FENACRATE (listed in **section 6**)
- if you have previously developed breathing problems (asthma, bronchospasm), skin reactions (hives), runny nose, or swelling of the face or tongue after taking/using diclofenac or acetylsalicylic acid (aspirin) or other non-steroidal anti-inflammatory drugs (e.g. ibuprofen)
- in the third trimester of pregnancy (see **Pregnancy**)

- if you have porphyria (a group of disorders that can cause nerve or skin problems).

Warnings and precautions:

Take special care with FENACRATE:

Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds.

FENACRATE should only be applied to the skin and should not be taken by mouth.

FENACRATE should not come into contact with eyes.

Stop the treatment if a skin rash develops after applying FENACRATE.

Do not use FENACRATE under airtight occlusive dressings (i.e. a dressing that does not allow air or moisture in). It may be used with a non-occlusive dressing (i.e. a dressing that allows the wound to breathe).

Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.

Due to an increased possibility of side effects, take care if you are using any other medicine containing diclofenac or painkillers known as NSAIDs, such as aspirin or ibuprofen.

Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.

If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.

Do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with FENACRATE burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children and adolescents:

FENACRATE is contraindicated in children under 12 years.

Other medicines and FENACRATE:

Always tell your healthcare provider if you are taking any other medicine this includes all complementary or

traditional medicines).

Tell your doctor if you are taking:

- Aspirin (for pain and inflammation)
- Lithium (used to treat mood disorders)

Pregnancy and breastfeeding:

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 healthcare provider for advice before you use FENACRATE.

Pregnancy:

Do not use FENACRATE during the third trimester of pregnancy as it could harm your unborn child or cause problems at delivery. During the first and second trimester of pregnancy, FENACRATE should be used only after consultation with your doctor.

Breastfeeding:

Use FENACRATE only under medical advice during breastfeeding as diclofenac passes into breast milk in small amounts. Do not apply FENACRATE on the breasts if you are a nursing mother nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines:

FENACRATE has no or negligible influence on the ability to drive or to use machines.

FENACRATE contains benzyl alcohol:

FENACRATE contains benzyl alcohol which may cause mild skin irritation.

3. HOW TO USE FENACRATE:

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

Always use FENACRATE exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

FENACRATE is used 3 to 4 times daily.

Depending on the size of the affected site to be treated, a cherry or walnut-sized quantity, corresponding to 2 to 4 g of gel is required.

How to apply:

FENACRATE is for use on the skin only.

Apply the gel to the affected parts of the body thinly and rub gently into the skin.

After application you should wash your hands, unless they are the site being treated.

Duration of treatment:

The duration of use depends on the symptoms and the underlying disease. If symptoms worsen or do not improve after 7 days, a doctor should be consulted. It is recommended that treatment be reviewed after 2 weeks.

If you use more FENACRATE than you should:

An overdose is unlikely to happen if you use more FENACRATE than you should, because the absorption into the blood stream is low when used on the skin. If the recommended dose is significantly exceeded when used on the skin, the gel should be removed and washed off with water.

If you accidentally swallow FENACRATE, contact your doctor or pharmacist who will decide on the appropriate measures. If neither is available, contact the nearest hospital or poison centre.

If you forget to use FENACRATE:

Apply it as soon as you remember. Do not use a double dose to make up for a forgotten application.

If you have any further questions on the use of FENACRATE, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS:

FENACRATE can have side effects.

Not all side effects reported for FENACRATE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FENACRATE, please consult your healthcare provider for advice.

If you experience any of the following signs of allergy, stop using FENACRATE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- skin rash with blisters; hives
- wheezing, shortness of breath or feeling of tightness in the chest (asthma)
- swelling of the face, lips, tongue or throat.

These are all very serious side effects. If you have them, you may have had a serious reaction to FENACRATE. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- skin rash; itching; reddening; eczema; dermatitis (inflammation of the skin) including contact dermatitis.

Less frequent side effects:

- skin peeling, discolouration of skin
- pustular rash (pus filled pimples), sensitivity to light with appearance of skin reactions after exposition to sunlight.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the **Adverse drug reaction and quality problem reporting form**, found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/. By reporting side effects, you can help provide more information on the safety of FENACRATE.

5. HOW TO STORE FENACRATE:

Store all medicines out of reach of children.

Do not store above 25 °C.

Store in the original tube in order to protect from light.

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

Return all unused medicine to your pharmacist.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

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What FENACRATE contains:

The active substance is diclofenac.

1 g contains 11,6 mg diclofenac diethylamine corresponding to 10 mg diclofenac sodium.

The other ingredients are carbomer, cocoyl caprylocaprate, macrogol cetostearyl ether, liquid paraffin, diethylamine, isopropyl alcohol, propylene glycol (E1520), fragrance (containing citronellol, geraniol, benzyl alcohol, linalool, limonene, citral, farnesol, coumarin, eugenol), purified water.

What FENACRATE looks like and contents of the pack:

FENACRATE is a white to almost white, homogeneous gel, packed in aluminium laminated tubes, closed with PE seal and PP screw caps, available in pack sizes: 30g, 50g, 60g, 100g, 120g, 150g per tube.

Each tube is packed in an outer carton

Not all pack sizes may be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd.

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

2090

Tel: + 27 11 055 0200

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This leaflet was last revised in:

13 November 2023

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