● **Brand : Rufenac Gel 30g**	● **Font Size : 5.5pt.**	● **Date of Design : 14/1/2019**
● **Item Code : 20100069-05**	● **Location : 013**	● **Artist : UD**

Tube Specifications	**Colour Specification**
Rufenac Gel 30g.	PANTONE Reflex Blue C PANTONE 355 C PANTONE 150 C PANTONE Process Black C PANTONE 185 C

X:\OriginalArtworks A-Z\Rufenac\R\Gel\R Rufenac Gel 30g Tube FPE 20100069-05 013 CCF-19-005 Malawi.cdr

	ART	**PACKAGING**	**PD**	**RA**	**MEDICAL ADVISOR**	**CQA**
SIGN.& Date						
NAME						

Production Regulated Universal Artwork--- For Ghana, Zambia, Cameroon, Nigeria, Malawi

● Brand : Rufenac 30g gel Carton	● Font Size : 5.5pt.	● Date of Design : 14/1/2019
● Item Code : 20200808-04	● Location : 013	● Artist : UD
Carton Specifications	● CCF/19/005	**Colour Specification**
Size: 138 (L) x 25 (W) x 33 (H) mm		C M Y K

X:\OriginalArtworks A-Z\Rufenac\R\Gel\R Rufenac Gel 30g IC FPE 20200808-04 013 CCF-19-005 Malawi.cdr

	ART	PACKAGING	PD	RA	MEDICAL ADVISOR	CQA
SIGN.& Date						
NAME						

RUFENAC GEL
(Diclofenac Diethyl Ammonium Gel)

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RUFENAC GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Chemical Name	Approved Name (if any)	Quantity per dosage unit in % w/w	Active / Non- active
Diethylammonium 2-[(2,6-dichloroanilino)phenyl] acetate.	Diclofenac Diethylammonium salt BP*	1.160	Active
Methyl 2-hydroxybenzoate	Methyl Salicylate BP	3.000	Active
(1R,2S,5R)-5-methyl-2-(1-methylethyl)-cyclohexanol.	Levomenthol BP	2.000	Active
Excipients			
---	Acrypol 980 In-House	1.200	Thickening agent
---	Acrysol 140 USP/NF	15.000	Solubilizer
---	Disodium Edetate BP	0.030	Chelating agent
---	Methyl Hydroxy Benzoate (Methyl Paraben) BP	0.060	Antimicrobial Preservative
---	Propyl Hydroxy Benzoate (Propyl Paraben) BP	0.025	Antimicrobial Preservative
---	Triethanolamine BP	0.714	Emulsifying agent
---	Purified water (q.s) BP	100.000	Solvent

* 1.16 % w/w Diclofenac Diethylammonium Salt BP. equivalent to 1% w/ w Diclofenac Sodium BP.

Note:

BP : British Pharmacopoeia

USP : United states Pharmacopoeia

IH : In house specifications

3. PHARMACEUTICAL FORM

Topical Gel

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Rufenac Gel is indicated in quick relief from pain and inflammation due to musculoskeletal disorders such as rheumatoid arthritis, osteoarthritis, spondylitis, peri-articular disorders such as bursitis, tendonitis and soft tissue disorders such as sprains, strains and other painful conditions such as renal colic, dysmenorrhea and acute gout.

4.2 Posology and method of administration

Directions for use:

Rufenac Gel should be applied gently in small quantity, approximately in one inch layer, on the intact skin of affected site. It should be rubbed till it disappears.

Dosage: Rufenac Gel should be applied 3-4 times a day.

4.3 Contraindications

(a) Hypersensitivity to diclofenac and other ingredients of the preparation.

(b) History of asthma, urticaria, other allergic reactions with other NSAIDs or aspirin.

(c) During perioperative period of coronary artery bypass surgery.

4.4 Special warnings and precautions for use

i) General: May increase serious cardiovascular & GI events especially in susceptible/old age patients or if utilized for longer time.

ii) Pregnancy: Rufenac Gel should be avoided in late pregnancy.

Rufenac Gel may inhibit uterine contraction therefore should be avoided during labour and delivery of child.

iii) Nursing mothers: Rufenac Gel is not recommended to nursing mothers.

iv) Pediatric use: Safety and effectiveness in pediatric patients have not been established.

v) Geriatric use: Elderly patients are more likely to have decreased renal function, care should be taken when using Rufenac Gel in the elderly, and it may be useful to monitor renal function.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of aspirin and anticoagulants may result in an increased GI bleeding.

4.6 Pregnancy and lactation

Fertility

There are no data available on the use of topical formulations of diclofenac and its effects on fertility in humans.

Pregnancy

The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-fetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, diclofenac should not be given unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the fetus to:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

The mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour. Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Voltarol Emulgel no effects on the suckling child are anticipated. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Voltarol Emulgel should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Use of large amounts of Rufenac Gel can lead to irritant or allergic contact dermatitis.

4.9 Overdose

It is unlikely that a sufficient volume of the gel could be ingested to cause any medical problems. In the event of accidental eye contact, wash with Luke warm water.

5. PHARMACOLOGICAL PROPERTIES

Pharmacological category: Topical products for joint and muscular pain, anti-inflammatory preparations, Non-steroids for topical use

ATC code: M02A A15

5.1 Pharmacodynamic properties

Rufenac gel is a non-steroidal anti-inflammatory (NSAID) and analgesic preparation designed for external application. Due to an aqueous-alcoholic base the gel exerts a soothing and cooling effect.

5.2 Pharmacokinetic properties

When Rufenac gel is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Rufenac gel.

After topical administration of Rufenac gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of Rufenac gel.

5.3 Preclinical safety data

No additional data of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acrypol 980 In-House, Acrysol 140 USP/NF, Disodium Edetate BP, Methyl Hydroxy Benzoate (Methyl Paraben) BP, Propyl Hydroxy Benzoate (Propyl Paraben) BP, Triethanolamine BP and Purified water (q.s) BP.

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

6.5 Nature and contents of container

30 gm aluminium collapsible tube packed in inner carton along with a leaflet.

6.6 Special precautions for disposal and other handling

None

7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

8. MARKETING AUTHORISATION NUMBER

Application for granting renewal of registration certificate

9. DATE OF FIRST AUTHORISATION

Application for granting renewal of registration certificate

10. DATE OF UPDATE OF TEXT

Sept. 2023