# SUMMARY OF PRODUCT CHARACTERISTICS

## 1.Name of the medicinal product

**VOLTIKA PLUS GEL**

Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate & Menthol Gel

## 2. Qualitative and quantitative composition

Linseed oil

BP..... 3.0 % w/w

Diclofenace Diethyl Ammonium BP.. 1.16 % w/w
Eq. to Diclofenac ..... 1.00 % w/w
Methyl Salicylate BP..... 10.0 % w/w
Menthol BP..... 5.0 % w/w
Preservative:
Benzyl Alcohol BP (As preservative) 1.0 % w/w
Gel Base ..... Q.S.

For full list of excipients, see section 6.1

## 3. PHARMACOLOGICAL DOSAGE FORM:

Gel for Topical use; White smooth Gel

## 4. Clinical Particulars

### 4.1 Therapeutic indications

Indicated to provide relief from sprains & strains, inflammation and pain due to musculoskeletal disorders.

### 4.2 Posology and method of administration

Apply a drop of gel onto the affected area and rub onto the skin. The amount of gel required will vary depending on the size of the area to be treated . Wash hands after use.

### 4.3 Contraindications

Patients with or without chronic asthama in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetlalicylic acid) aspirin (or other non-steroidal anti- inflammatory drugs) NSAIDs

Contraindicated in patients with hypersensitivity to any of the ingredients of this product. Third trimester of pregnancy

### 4.4 Special warnings and precautions for use

For external use only.Do not use with a heating pad. Keep away from children to avoid accidental poisoning. Do not bandage tightly. Do not swallow. If swallowed, induce vomiting and call a physician. Keep away from eyes, mucous membranes, broken or irritated skin. If skin redness or irritation develops, pain lasts for more than 10 days, or with arthritis -like conditions in children under 12, do not use and call a physician.

**PRECAUTIONS:**

**VOLTIKA PLUS GEL** should be applied only to intact skin surface and not to skin wounds or open injuries. It should not come in contact with eyes or mucous membranes.

Apply gel only to intact skin surface. Avoid contact with eyes.

### 4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of Diclofenac from topical application is very low such interactions are very likely. There are no known interactions with VOLTIKA PLUS GEL, but for a list of interactions known with oral diclofenac the data sheet for oral dosage forms should be consulted.

### 4.6 Fertility, pregnancy and lactation

The doctor will decide whether **VOLTIKA PLUS GEL**is safe to use during pregnancy and breastfeeding and therefore this Gel should only be used if it has been prescribed by a doctor.Third trimester of pregnancy.

### 4.7 Effects on ability to drive and use machines

Voltika Plus Gel cream has no influence on the ability to drive and use machines.

### 4.8 Undesirable effects

Occasionally local side effects such as skin rash, itching and reddening may be observed.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via https://pv.pharmacyboardkenya.org

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Voltika plus gel contains diclofenac that is a benzene-acetic acid derivative belonging to nonsteroidal anti-inflammatory drug (NSAID) class of drugs. The name is derived from its chemical name 2-(2,6-dichloranilino) phenylacetic acid. It has the odour of menthol and methyl salicylate.
Diclofenac Diethylamine is systemically absorbed through the skin, it inhibits the enzyme cyclo-oxygenase, thus reducing the formation of PGE2. Moreover, it also increases the uptake of Arachidonic acid into the cellular pool. Methyl salicylate is a known anti-inflammatory agent. Linseed oil helps in reducing inflammation.

Diclofenac works by blocking the effect of chemicals called cyclo-oxygenase (COX) enzymes. These enzymes help to make other chemicals in the body, called prostaglandins. Some prostaglandins are produced at sites of injury or damage causing pain and inflammation. By blocking the effect of COX enzymes, fewer prostaglandins are produced, which means pain and inflammation are eased. The linseed oil helps in the penetration of the diclofenac through the skin. Methyl salicylate also acts as an analgesic and menthol gives relief due to its cooling effect.

### 5.2 Pharmacokinetic properties

The gel can be absorbed from normal intact skin. The extent of percutaneous absorption of gel is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

After cutaneous application of Diclofenac Gel a rapid onset of Diclofenac absorption can be observed leading to measurable plasma levels as early as 30 minutes. The achieved systemic concentrations of diclofenac are about 50 times lower than those achieved following oral administration of equivalent amount of diclofenac.

Diclofenac has potent anti-inflammatory, analgesic and antipyretic actions. It inhibits the enzyme, cyclooxygenase, thus resulting in reduced synthesis of prostaglandin precursors.

Absorption: Rapidly absorbed (oral solution, rectal suppository, IM); more slowly (entericcoatedtab).

Distribution: Penetrates synovial fluid; enters breast milk (small amounts). Protein-binding: >99%.

Metabolism: Extensively hepatic; converted to metabolites.

Excretion: About 60% excreted in urine as glucuronide and sulfate conjugates; 35% in bile; 12 hr (elimination half-life).

## 6. Pharmaceutical particulars:

### 6.1. List of excipients:

| | |
|---|---|
| **1.** | Benzyl Alcohol |
| **2.** | Polysorbate 80 |
| **3.** | Butylated Hydroxy Toluene |
| **4.** | Butylated Hydroxy Anisole |
| **5.** | Cremophor RH 40 |
| **6.** | Citric Acid Monohydrate |
| **7.** | Disodium EDTA |
| **8.** | Carbopol 940 |
| **9.** | Isopropyl Alcohol |
| **10.** | Propylene Glycol |
| **11.** | Triethanolamine |
| **12.** | Triethanolamine |

**6.2. Incompatibilities:**
Not applicable

**6.3. Shelf-life:**
36 Months

**6.4. Special precaution for storage:**
Store below 30°C. Protect from light.

**6.5. Nature and contents of container:**
Aluminium collapsible tubes having closed nozzle lacquered at inner surface having 30 gm capacity after sealing.

**7. Marketing authorization holder:**
Mihika Pharmaceuticals
506, Parmeshwari Centre, 18 Dalm1a Estate, Mulund (W), Mumbai-400080 India

**8. Marketing authorization number**
H2022/CTD8630/15280

**9. Date of registration or renewal**
27/10/2022

**10. Date of revision of text**
27/10/2022