## Medifen Gel

Diclofenac Sodium 1% W/W

#### **COMPOSITION:**

**Medifen** Gel: Each gram gel contains Diclofenac Diethylamine BP equivalent to Diclofenac Sodium 10 mg.

## PHARMACOLOGY:

**Medifen** Gel (Diclofenac Sodium) is a potent Non-Steroidal Anti-Inflammatory Drug (NSAID) with marked analgesic and antipyretic properties. The actions of Diclofenac appear to be associated principally with the inhibition of prostaglandin synthesis. Diclofenac Sodium inhibits the synthesis of prostaglandins by inhibiting cycloxygenase enzyme. Diclofenac Sodium is well absorbed from skin after topical administration. About 60 % absorption occurs within 1.5 hours. Peak plasma concentration achieved within 6.5 hours.

#### INDICATION:

**Medifen** Gel is used for the local symptomatic relief of pain and inflammation in: a) Trauma of the tendons, ligaments, muscles and joints, e.g., due to sprains, strains and bruises, b) Localized forms of soft tissue rheumatism.

# DOSAGE AND ADMINISTRATION:

Depending on the size of the area to be treated, 2-4 gm of **Medifen** Gel should be applied to the skin 3-4 times daily to the affected area and rubbed in lightly. **Medifen** Gel may also be given in addition to further treatment with other dosage forms of Diclofenac.

### **CONTRAINDICATION:**

Patients with hypersensitivity to Diclofenac Sodium. Patients with asthma and urticaria are also contraindicated to use Diclofenac gel.

#### **SIDE EFFECTS:**

Diclofenac Sodium is well tolerated. Skin irritation occurs in rare case.

#### **PRECAUTIONS:**

**Medifen** Gel should not be allowed to come in contact with the eyes or mucous membranes. After application, the hands should be washed unless they are the sites being treated. Not to be taken by mouth.

## **USE IN PREGNANCY AND LACTATION:**

USFDA pregnancy category D. Topical Diclofenac should not be used during pregnancy, because it can cause premature closure of Ductus Arteriosus.

# PHARMACEUTICAL PRECAUTION:

It should be stored in a cool and dry place, protected from light and moisture.

#### **HOW SUPPLIED:**

Medifen Gel: Each tube contains 10 gm of cream.

## Manufactured by:

