

# Xicotil

Tenoxicam BP 20 mg

## Composition:

**Xicotil Tablet:** Each film coated tablet contains Tenoxicam BP 20 mg.

## Pharmacology:

Tenoxicam is a non-steroidal anti-inflammatory drug (NSAID) with anti-inflammatory, analgesic and antipyretic properties. It also inhibits platelet aggregation. Tenoxicam inhibits prostaglandin biosynthesis. In-vitro tests of leukocyte peroxidase suggest that Tenoxicam may act as a scavenger for active oxygen at the site of inflammation. Tenoxicam is a potent in-vitro inhibitor of human metalloproteinases, which induce cartilage breakdown. These pharmacological effects explain, at least in part, the therapeutic benefit of Tenoxicam in the treatment of painful inflammatory and degenerative disorders of the musculoskeletal system. Antipyretic action may occur by central action on the hypothalamus, resulting in peripheral dilation, increased cutaneous blood flow and subsequent heat loss.

## Indications:

Xicotil is indicated for the treatment of the painful inflammatory and degenerative disorders of the musculoskeletal system: rheumatoid arthritis, osteoarthritis, arthrosis, ankylosing spondylitis, extra-articular disorders, e.g. tendinitis, bursitis, periarthrititis of shoulders (shoulder-hand syndrome) or hips, strains and sprains. It is also effective in post-operative pain, acute gout & primary dysmenorrhea.

## Dosage & administration:

**Standard dose:** For all indications except primary dysmenorrhea, post-operative pain and acute gout, a daily dose of 20 mg should be given at the same time of day. *Primary dysmenorrhea:* 20 to 40 mg once daily. *Post-operative pain :* 40 mg once daily up to five days: *Acute attacks of gout:* 40 mg once daily for two days followed by 20 mg once daily for a further five days. In chronic disorders, daily doses higher than 20 mg are not recommended. **Special dosage instruction:** Dosage should be minimized in the elderly and in patients with renal impairment. Because of lack of clinical experience, no dosage recommendations have so far been established for children and adolescents. **Xicotil tablets should be taken with a glass of water. It is preferable to take this medicine during or immediately after a meal.**

## Contraindications:

Tenoxicam is contraindicated in patients with known hypersensitivity to Tenoxicam, to any component of the product or to other non-steroidal anti-inflammatory drugs (NSAIDs). Tenoxicam is relatively contraindicated in patients with liver dysfunction, asthma, rhinitis, GI bleeding and peptic ulcer.

## Precautions:

Patients with uncontrolled hypertension, congestive heart failure, established ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease should only be treated with Tenoxicam after careful consideration. The use of tenoxicam with concomitant NSAIDs, including cyclo-oxygenase-2 selective inhibitors should be avoided. NSAIDs should be given with care to patients with a history of IBD as their condition may be exacerbated. Caution is advised in patients receiving concomitant medications which could increase the risk of ulceration or bleedings, such as oral corticosteroids, anticoagulants, SSRIs or antiplatelet agents (e.g. Aspirin).

## Side effects:

Tenoxicam is well tolerated in the recommended dosage. Usually the undesirable effects reported are mild and transient. These are gastrointestinal disorders: gastric, epigastric and abdominal discomfort, dyspepsia, heartburn, nausea; nervous system disorders: dizziness, headache. Vertigo, sleep disturbance, palpitation & urticaria may occur rarely.

## Drug interactions:

Concurrent treatment with salicylates or other NSAIDs may increase the risk of undesirable reactions. There is an increased risk of gastrointestinal bleeding when anti-platelet agents and selective serotonin-reuptake inhibitors are combined with Tenoxicam. It should not be administered concurrently with potassium sparing diuretics as they may cause hyperkalemia & renal failure. It may attenuate the antihypertensive effects of alpha-adrenergic blockers and ACE-inhibitors.

## Use in special group:

### Pregnancy:

No data with Tenoxicam exist in pregnant women.

### Nursing mothers:

Based on findings from single dose administration, a very small amount of Tenoxicam passes into breast milk. There is no evidence of adverse reactions in breast-fed infants of mothers taking Tenoxicam. Nevertheless, infants should be weaned or the medicine discontinued.

## Storage:

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

## Packing:

**Xicotil Tablet:** Each box contains 30's tablets in blister pack.

Manufactured by:  
**ARISTOPHARMA LTD.**  
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