

# NORACIN®

## DESCRIPTION

**NORACIN** is the brand name of Norfloxacin, a synthetic Fluoroquinolone derivative with a broad spectrum antibacterial activity.

Each **NORACIN** film coated tablet contains 400 mg of Norfloxacin.

## CHEMISTRY

Norfloxacin is 3 - quinolinecarboxylic acid, 1 - ethyl - 6 - fluoro - 1,4 - dihydro - 4 - oxo - 7 - (1 - piperazinyl).

## SITE AND MODE OF ACTION

**NORACIN** is bacteriostatic at low concentrations and bactericidal at higher concentrations. It acts by inhibiting the A subunit of the essential enzyme DNA gyrase, essential for the ATP dependent coiling and supercoiling of bacterial DNA. It inhibits the relaxation of supercoiled DNA and promotes double stranded DNA breakage.

**NORACIN** is rapidly but incompletely absorbed from the GIT in the fasting state, presence of food may slightly decrease or delay absorption.

## INDICATIONS

- Urinary tract infections: **NORACIN** is indicated in adults in the treatment of complicated and uncomplicated urinary tract infection caused by *Citrobacter freundii*, *Enterbacter cloacae* ( *Aerobacter cloacae*), *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, indole - positive *Proteus* species (including *P. Vulgaris*, *Providencia rettigii* and *Morganella morganii* - *Proteus morganii*), *Pseudomonas aeruginosa*, *S. Epidermidis* and group D. *Streptococci*.

## USES

In addition to the preceding indications **NORACIN** is used in:

- Gonorrhoea or gonococcal urethritis: **NORACIN** is used in the treatment of uncomplicated gonorrhoea and gonococcal urethritis caused by penicillinase producing *Neisseria gonorrhoea*.
- Gastroenteritis: **NORACIN** is used as primary agent in the treatment of bacterial gastroenteritis caused by *Aeromonas hydrophila*, enterotoxigenic *E.coli*, *Salmonella* species, *Shigella flexneri* (S. *Paratyphenteriae*), *S. sonnei* (*Bacterium Sonnei*) and vibrio parahaemolyticus.

## DOSAGE

Usual Adult Dose:

- Urinary Tract Infections (uncomplicated): 400 mg every 12 hours for 3 days.
- Urinary Tract Infections (complicated): 400 mg every 12 hours for 10 - 21 days.
- Bacterial gastroenteritis : 400 mg every 8 - 12 hours for 5 days.
- Gonorrhoea or Gonococcal Urethritis: 800 mg as single dose.

Use Adult prescribing Limits:

- Urinary tract infections - Up to maximum of 800 mg daily.
- Gastroenteritis - Up to 1.2 grams daily.

Use in Pediatrics:

- **NORACIN** should not be used in children because it causes arthropathy in juvenile animals. (See warnings).

## Note

- Adults with impaired renal function (creatinine clearance < 30 ml/minute per 1.73 M2) require a reduction in dose as follows:

Urinary tract infection, 400 mg once a day for seven to ten days ( uncomplicated) or ten to twenty one days (complicated).

- **NORACIN** is preferably taken with a full glass of water (240 ml) one hour before or two hours after meals, since presence of food delays its absorption.

## USE IN PREGNANCY

Adequate studies in human have not been done. Since Norfloxacin causes

arthropathy in immature animals, it should not be used in pregnant women.

## USE IN LACTATION

**NORACIN** has not been detected in breast milk when it was given to nursing mothers in low doses (200 mg). However, since the studied dose was low and because of the potential for serious adverse reactions in nursing infants it is advised to discontinue the medicine or discontinue nursing, taking into account importance of drug to the mother.

## ADVERSE REACTION

- Most common: Drowsiness, gastrointestinal disturbance (abdominal or stomach pain or upset, constipation, loss of appetite, nausea or vomiting), heartburn, rash.
- Less common: Diarrhea, dry mouth, photosensitivity, trouble in sleeping and CNS effects (dizziness, light headedness, headache and mental depression, insomnia).
- Exacerbation of symptoms of myasthenia gravis.

## NOTE

Crystalluria is very unlikely to occur unless the patient's urine has become alkaline.

## INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

**NORACIN** may interfere with physiological laboratory test values:

- May increase concentration of:  
Blood urea nitrogen (BUN), serum alanine amino transferase (ALT SGPT), serum alkaline phosphatase, serum aspartate amino transferase (AST SGOT), serum creatinine, serum lactate dehydrogenase.
- May decrease concentration of hematocrit (HCT).

## CONTRAINDICATION

History of hypersensitivity to Norfloxacin or to any chemically related quinolone antibacterial agent.

## WARNINGS

- Norfloxacin should not be used in children or pregnant women since it has showed to cause arthropathy in immature animals.
- Risk benefits should be considered when the following medical problems exist:  
- History of seizures.  
- Renal impairment, however adjustments in dosage must be made (see DOSAGE).

□ Norfloxacin should be used with caution in patients with myasthenia gravis.

## PRECAUTIONS

- Patient should drink sufficient fluids.
- Patients should continue medicine for full time of treatment.
- Avoid concurrent use with antacids or take the antacid at least 2 hours after **NORACIN** administration.

## PRESENTATIONS

- Boxes of 14 film coated blistered tablets.
  - Hospital packs of different presentations.
- Do not store above 30° C.  
Do not use after the expiry date shown on the package.



## THIS IS A MEDICAMENT



- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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COUNCIL OF ARAB HEALTH MINISTERS  
UNION OF ARAB PHARMACISTS

Prescribing Information Available Upon Request



THE JORDANIAN PHARMACEUTICAL MANUFACTURING CO.(P.L.C.)  
P.O. BOX 94, NAOR 11710, JORDAN