

ROXAMED[®] roxithromycin

ROXAMED[®] is roxithromycin, a semi-synthetic macrolide, with a broad spectrum bactericidal activity against many Gram positive bacteria, Gram negative bacteria, anaerobes, mycobacteria, chlamydia and mycoplasma.

PHARMACOLOGY :

ROXAMED[®] is stable in acidic media; and well absorbed following oral administration resulting in high serum levels and long half-life . Peak concentration of about 6-8 µg/ml is reached after 2.2 hrs after a single dose of 150 mg in fasting subjects. Tissue distribution is extensive and sustained as shown by the high concentrations measured in lung, prostate, ovaries, kidney and skin. Also, clinically, effective concentrations were determined in sputum and saliva . The elimination half-life is about 8-13 hrs.

INDICATIONS :

ROXAMED[®] is indicated for the treatment of the following infections:

- 1 - Upper respiratory tract infections including tonsillitis, sinusitis, rhinopharyngitis, and otitis media.
- 2 - Lower respiratory tract infections including pneumonia, bronchitis, bronchiolitis, and alveolitis.
- 3 - Genitourinary tract infections with exception of gonococcal infections.
- 4 - Skin and soft tissue infections.
- 5 - Prophylaxis of meningococcal meningitis .

DOSAGE :

One tablet 150 mg twice daily before meals.

CONTRAINDICATIONS :

Hypersensitivity to macrolides and concomitant use with ergot derivatives.

SIDE EFFECTS :

Nausea, vomiting, gastralgia, diarrhea, and skin rash.

PRECAUTIONS :

Roxithromycin should not be administered to patients with hepatic dysfunction .There is no need to adjust dosage in patients with renal impairment.

Pregnancy : The safety of roxithromycin in pregnant women has not been established.

Lactation : Very small quantities of roxithromycin have been found in breast milk.

DRUG INTERACTIONS :

- The administration of roxithromycin in association with ergotamine-type compounds has developed ergotism with possibility of necrosis in the extremities.
- It also interacts with dopamine, leading to an increase in antiparkinson activity or to increased signs of dopamine toxicity.
- Roxithromycin may produce an increase in cyclosporine blood levels.

OVERDOSAGE :

There is no special antidote for roxithromycin . In case of overdosage, gastric lavage and supportive treatment should be considered.

PRESENTATION :

ROXAMED[®] 150 tablets : Pack of 10 film coated tablets.

Each film coated tablet contains 150 mg roxithromycin.

STORAGE CONDITIONS :

Store in a dry place below 25° C.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health , and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctors prescription, method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you .
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

P100590 - 9/98

Manufactured by Dar Al Dawa , Na'ur - Jordan