QARI®

Rufloxacin

COMPOSITION
Each tablet contains:
Principal agent: 200 mg rufloxacin hydrochloride.
Excipients: cellulose microcrystalline, maize starch, lactose monohydrate, croscarmellose sodium, pregelatinised maize starch, magnesium stearate, hypromellose, titanium dioxide, macrogol 400.

PHARMACEUTICAL FORM Coated tablets

PACKAGING QARI: box of 6 coated 200 mg tablets

PHARMACO-THERAPEUTIC ACTIVITY Antibacterial quinolone (fluoroquinolone)

MARKETING AUTHORIZATION HOLDER
MEDIOLANUM farmaceutici S.p.A. - Via San Giuseppe Cottolengo 15 - Milan - Italy

PRODUCER
DOPPEL Farmaceutici S.r.l. - Via Volturno 48, Quinto dé Stampi - Rozzano (MI)

ANTIBACTERIAL SPECTRUM
Rufloxacin antibacterial spectrum is as follows:
Organisms usually susceptible: Escherichia coli, Proteus, Proteus vulgaris, Proteus mirabilis, Klebsiella, Klebsiella oxytoca, Enterobacter aerogenes, Citrobacter diversus, Salmonella, Salmonella typhi, Shigella, Morganella morganii, Yersinia enterocolitica, Haemophilus influenzae, Haemophilus parainfluenzae, Aeromonas, Moraxella catarrhalis, Plesiomonas, Neisseria gonorrhoeae, Neisseria meningitidis, Staphylococcus aureus meticilline sensible, Staphylococcus saprophyticus, Mycoplasma pneumoniae, Mycoplasma hominis, Legionella pneumophilia, Listeria monocytogenes, Ureaplasma urealyticum, Peptococcus, Klebsiella pneumoniae, Providencia, Providencia rettgeri, Enterobacter, Enterobacter cloacae, Citrobacter, Citrobacter freundii, Serratia, Serratia liquefaciens, Serratia marcescens, Acinetobacter anitratus, Staphylococcus epidermidis, Staphylococcus aureus, Chlamydia pneumoniae, Chlamydia trachomatis.
Organisms not always susceptible: Providencia stuartii, Acinetobacter, Clostridium perfrigens, Brucella melintensis.
Organisms usually resistant: Pseudomonas aeruginosa, Streptococcus pneumoniae, Streptococcus pyrogenes, Enterococcus, Alcaligenes, Staphylococcus aureus meticilline resistant, Mycobacterium tuberculosis, Mycobacterium avium, Streptococcus, Bacteroides fragilis, Clostridium, Clostridium difficile.

THERAPEUTIC INDICATIONS
QARI is suitable for use in the treatment of infections of the lower respiratory tracts and urinary tracts carrying germs sensitive to rufloxacin.

CONTRAINDICATIONS
Individual hypersensitivity to the drug or to other chemotherapeutic agents of the quinolonese type.
As with other fuoroquinolones, QARI should not be given to patients with epilepsy or with a history of convulsions. Previous tendinopathy with fluoroquinolones.
Since Qari's safety has not been established regarding the possibility of damage to the joint cartilages in developing organisms, QARI should not be administered during pregnancy, during breast feeding, to paediatric patients, nor to young people whose skeletal growth is not complete.

PRECAUTIONS DURING USE
As QARI, like other fuoroquinolones, is mainly excreted through the kidneys, it must be used with great care with patients with kidney problems; in patients with glomerular filtration rate of less than 30 ml/min it is advisable to give QARI on alternate days.
As with other fuoroquinolones, QARI should be used with care in elderly patients, in patients with severe hepatic impairment and in patients with disturbances of the central nervous system. As with other products of the same type, photosensitive phenomena have been exceptionally recorded; it is therefore advisable that patients being treated with QARI do not expose themselves to radiation from direct sunlight or to radiation from UVA rays (sunlamps) during the treatment.
As with other antibacterial agents, prolonged use of the product may increase the development of resistant microorganisms, including fungi, and this requires appropriate therapeutic measures.
QARI may alter alertness even when used at normal dose, so that it may influence driving or the use of machinery.

INTERACTIONS
As with other quinolones, the antacids with a base of aluminium or magnesium hydroxide reduce the absorption of the drug; to minimise this effect they should be administered at

least 4 hours before or after QARI. Unlike what observed with other fuoroquinolones, no evidence in man of interactions between QARI and theophylline and its derivatives has been observed. In case of prolonged treatment it may be advisable as a precaution to monitor the plasma levels of theophylline.
QARI has no influence on the elimination of caffeine. No drug interactions have been noted in the case of other polytherapies. It is not advisable to take quinolones or NSAIDs at the same time.

WARNINGS

In rare cases during the course of treatment with fuoroquinolones, inflammations and lesions may occur with rupture of the tendons.
In case of pain and/or oedema of the Achilles tendon (at ankle level), stop treatment, rest completely and contact your own doctor for appropriate therapeutic action.
Factors predisposing to tendinitis or rupture of the tendons are: over 60 years of age, strong physical exercise, long term treatment with corticosteroids, early deambulation phase of bed confined patients.
If serious or persistent diarrhoea is present during or after treatment, your doctor should be informed immediately, because there may be a possibility of a very serious pseudomembranous colitis, which would require the immediate suspension of treatment and the adoption of an appropriate treatment (e.g. oral vancomycin 4x250 mg/day).

Keep the medicine away from children.

DOSAGE, METHOD AND TIME OF ADMINISTRATION

The long half life of QARI - approximately 35 hours - allows a single daily dosage (once-a-day).
The recommended dosage is: 2 tablets taken together on the first day and one tablet a day on the following days. The length of the treatment depends on the severity of the infection as well as the clinical and bacteriological course; in general 5 or 10 days treatment is sufficient. Considering the long half life, the antibacterial cover remains for 2-3 days after treatment stops; therefore it is not necessary to continue treatment after the fever has subsided or the clinical symptoms have disappeared. For treatment of cystitis which has no complications a single dose of 400 mg of QARI is sufficient (2 tablets taken once only).
Elderly patients: the dosage should not be altered if the renal function is normal with regard to the age of the patient.
Impaired renal function: the frequency with which the drug should be taken will be reduced in proportion to the amount of renal failure (see Precautions during use).
Impaired hepatic function: a possible reduction in the dosage will be only considered in the cases of marked hepatic failure. The maximum length of treatment documented in clinical trials is four weeks. The use of the product is reserved for the treatment of adult patients.

OVERDOSE

No overdose cases have yet been reported; in such an event, normal measures are advised (emptying the stomach by induced vomiting or gastric lavage; the patient should be kept under strict observation and hydrated at the appropriate time).

UNDESIRED EFFECTS

The most frequent undesired effects observed in the clinical trials were:
- gastro-intestinal tract: epigastralgia, nausea, pyrosis, dyspepsia, diarrhoea, vomiting,
- nervous system: cephalgia, nervousness, anxiety, dizziness, insomnia, tremors, tiredness,
- hypersensitive reactions: skin reactions (exanthema, urticaria, erythema, rash) and pruritus.

When using the product, serious anaphylactic reactions are possible (from oedema of the tongue, oedema of the glottis, dyspnea, and arterial hypotension to dangerous shock).
From informal monitoring a few cases of tendinitis and ruptures of the tendons have been recorded following the use of rufloxacin.
Moreover, in exceptional cases, the following undesired effects have been recorded: dry mouth, flatulence, paresthesia, confusion, hallucinations, car buzzing, sweating, muscular pain and photosensitivity.
In the case of the appearance of undesired effects, the doctor will have to evaluate carefully whether or not discontinue the treatment.
Even if experience gathered up to now does not allow for a definitive evaluation of the possible undesired effects of QARI, its acceptability profile appears similar to the other quinolones; therefore the appearance during treatment of possible undesired reactions recorded for other drugs of the same class, even if not recorded for QARI, cannot be ruled out.
Please inform your own doctor or pharmacist of any undesired effect other than those indicated above.

ATTENTION: do not use the medicine after the expiry date shown on the box.

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