Rifadin®

RIFADIN is a semi-synthetic bactericidal antibiotic, effective both by oral and parenteral route, discovered in the Lepetit Research Laboratories.
The active principle in RIFADIN is rifampicin: 3-(4methyl-1-piperazinyl-iminomethyl) rifamycin SV.
Its antibacterial activity in vitro and in experimental infections is exerted against mycobacteria, including Mycobacterium tuberculosis and against many Gram-positive and Gram-negative microorganisms. A large clinical experience has confirmed these activities in infections due to microorganisms susceptible to rifampicin.
Rifampicin does not show cross-resistance with other antibiotics with the exception of the rifamycins and therefore is active also against microorganisms resistant to the former group. Due attention must be given to the possibility of emergence of resistant strains during treatment, sometimes within a short period of time; the incidence varies according to the bacterial species.
In man, after oral administration of 150-1200 mg, peak blood levels of rifampicin are reached around the 2nd hour and persist at appreciable values beyond the 8th and the 12th hours respectively with excellent distribution in the body tissues and fluids.
Elimination occurs mainly through the bile and urine, where very high concentrations are reached.

INDICATIONS
Infections caused by microorganisms susceptible to rifampicin and in particular due to Mycobacterium tuberculosis and other mycobacteria.
As recommended in general for a correct use of antibiotics, the susceptibility of the pathogenic microorganisms, or their possible primary or acquired resistance, should be determined by sensitivity tests. If the infection does not respond within a reasonable period of time, treatment should be changed and, in the event of a relapse, the administration of rifamycins is not recommended until preliminary bacteriological examinations have been made.

USE AND DOSAGE
RIFADIN for oral use
Available in capsules (of 150 mg and 300 mg of antibiotic), in tablets (of 450 mg and 600 mg of antibiotic) and in syrup (10 ml contain 200 mg of antibiotic).
The syrup is a preparation with pleasant taste which is particularly indicated in patients who have difficulty in swallowing the capsules or the tablets.
DOSAGE
Adults: In general 300 mg every 12 hours. If necessary, the daily dose may be increased up to 1200 mg.
Children: The recommended daily dose is 10-20 mg/kg body weight, divided in two equal administrations. It is recommended not to exceed the daily dose of 600 mg.
Instructions for use:
For a faster and more complete absorption it is recommended to take RIFADIN on an empty stomach, between meals.
In tuberculosis it is recommended to give a single daily dose of 600 mg (450 mg for subjects less than 50 kg), in conjunction with other antituberculous drugs. In the recently discovered cases the most effective treatment is the short term continuous chemotherapy regimen of 9 months duration with the above mentioned doses, in combination with isoniazide and, during the first 3 months, with a third antituberculous agent.
RIFADIN for I.V. infusion
Available in vial (600 mg of antibiotic) with an ampoule of solvent. It is recommended particularly when the clinical situation (surgery, altered gastroenteric absorption, etc.) or the patient's gastric tolerance does not permit or recommend oral administration of the antibiotic.
The solution is prepared by adding the ampoule of solvent to the vial of rifampicin and shaking vigorously without interruption for about 30 seconds. On complete disappearance of the foam this solution should be diluted immediately with 500 ml of 5% glucose solution. The solution thus prepared should be used within a few hours. It is recommended to adjust the drip rate so that the i.v. infusion takes about 3 hours.
DOSAGE
Non-specific infections:
For adults, the recommended daily dose is 600 mg.
Pulmonary tuberculosis:
In adults the recommended daily dose is 600 mg, usually in a single administration. The treatment of pulmonary tuberculosis with RIFADIN I.V. should always be combined with other antituberculosis drugs.

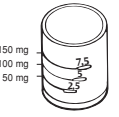
CONTRAINDICATIONS
RIFADIN must not be administered to patients with hypersensitivity to rifamycins, jaundice and during the first three months of ascertained or presumed pregnancy. During the remaining months of pregnancy and in early infancy, the drug should be administered in case of real necessity, under the direct control of the physician.

WARNINGS AND PRECAUTIONS
The administration of rifampicin may be accompanied by induction of the liver drug metabolizing enzyme systems. The metabolism of those substances that are substrates in these systems may be affected and in certain cases accelerated with the possible consequence of a reduced pharmacological effect. Changes with possible clinical signifiance have been reported regarding anticoagulants, oral antidiabetics, digitalis preparations and oral contraceptives. Adjustment of the dosage of these drugs may be required if they are given concurrently with RIFADIN, particularly at the beginning and end of the treatment with this antibiotic.
Women on oral contraceptives during treatment with RIFADIN should be advised to use non-hormonal methods of birth control since during combined treatment the contraceptive effect of hormonal ovariostatic preparations may be compromised, although only in rare cases.
The administration of the product should be carried out for limited periods of time and whenever possible at low doses and alternate administration of other therapeutical measures.
RIFADIN should be administered to patients with liver diseases, particularly in cases of chronic alcoholism and hepatic cirrhosis, only when necessary and under medical control. In these cases it is recommended to administer reduced doses of the antibiotic, as well as to keep at a minimum the use and dosage of any other drug in particular if potentially hepatotoxic, and to monitor the liver function.
For these patients, as well as for elderly subjects in poor nutritional condition and in early infancy, care is advised especially in cases of concomitant administration of isoniazide.
In patients on long term treatment with rifampicin periodic monitoring of the blood picture and liver function is recommended. In monitoring liver function the bromsulphtalein (BSP) test should not be carried out since rifampicin has a competitive action with regard to the elimination of bromsulphthalein and so a false impression of functional alteration of the liver might be given.
The frequency and severity of haematological type adverse reactions may be increased in case of concurrent administration of isoniazide. In the treatment of non-tuberculous infections, when a concomitant tuberculosis state is suspected, rifampicin should not be used until the diagnosis has been clearly made in order not to mask the tuberculosis process and not to provoke the development of mycobacterial resistance.
If RIFADIN is used in combination with oral PAS formulations containing bentonite as an excipient, the two drugs should not be administered concomitantly but with an interval of at least 8 hours.
Due to the very pleasant taste of the syrup it is recommended to keep the product out of the reach of children.
The administration of RIFADIN may produce a more or less marked reddish colouration of the urine, tears and sputum.
These phenomena are not cause for concern.
The syrup presentation contains sodium metabisulfite, a substance that may cause allergic type reactions and severe asthmatic episodes in certain susceptible people and particularly in asthmatics.

SIDE EFFECTS
The use of rifampicin has occasionally led to reports of gastrointestinal disturbances such as epigastric pain, anorexia, nausea, vomiting, meteorism, cramps and diarrhoea. Headache, somnolence, asthenia, vertigo, reduction of the power of concentration, visual disturbances, muscular weakness, pains in the extremities, menstrual disturbances have also been reported.
Secondary reactions of hypersensitivity have been observed with cutaneous rash, urticaria, pruritus, eosinophilia, ulcerative stomatitis and glossitis, and in isolated cases thrombocytopenia, leucopenia, haemolytic anaemia, hepatitis with jaundice, renal insufficiency, haematuria, haemoglobinuria, changes in bilirubin, alkaline phosphatase and transaminases levels, as well as of BSP tests.

PACKAGING
8, 50 and 100 capsules containing 150 mg of rifampicin.
8, 50 and 100 capsules containing 300 mg of rifampicin.
8 and 32 tablets containing 450 mg of rifampicin.
8 and 32 tablets containing 600 mg of rifampicin.
Syrup: Bottle of 60 ml containing 1.2 g of rifampicin (with measuring glass graduated at 2.5, 5 and 7.5 ml). The glass should be washed thoroughly with water after each dose of syrup.
Vial for I.V. infusion: box containing one vial of lyophilized rifampicin (600 mg) + one ampoule of solvent (10 ml).

The glass should be washed thoroughly with water after each dose of syrup.



Measuring glass graduated at 2.5, 5 and 7.5 ml

KEEP THE PRODUCT OUT OF THE REACH OF CHILDREN

Lepetit

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