RIFADIN®
(rifampin capsules USP) and
RIFADIN® IV
(rifampin for injection USP)
To reduce the development of drug-resistant bacteria and maintain the effectiveness of RIFADIN (rifampin capsules USP) and RIFADIN IV (rifampin for injection USP) and other antibacterial drugs, rifampin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

DESCRIPTION
RIFADIN (rifampin capsules USP) for oral administration contain 150 mg or 300 mg rifampin per capsule. The 150 mg and 300 mg capsules also contain, as inactive ingredients: corn starch, D&C Red No. 28, FD&C Blue No. 1, FD&C Red No. 40, gelatin, magnesium stearate, and titanium dioxide.

RIFADIN IV (rifampin for injection USP) contains rifampin 600 mg, sodium formaldehyde sulfoxylate 10 mg, and sodium hydroxide to adjust pH.

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CLINICAL PHARMACOLOGY
Oral Administration
Rifampin is readily absorbed from the gastrointestinal tract. Peak serum concentrations in healthy adults and pediatric populations vary widely from individual to individual. Following a single 600 mg oral dose of rifampin in healthy adults, the peak serum concentration averages 7 mcg/mL but may vary from 4 to 32 mcg/mL. Absorption of rifampin is reduced by about 30% when the drug is ingested with food.

Rifampin is widely distributed throughout the body. It is present in effective concentrations in many organs and body fluids, including cerebrospinal fluid. Rifampin is about 80% protein bound. Most of the unbound fraction is not ionized and, therefore, diffuses freely into tissues.

In healthy adults, the mean biological half-life of rifampin in serum averages 3.35±0.66 hours after a 600 mg oral dose, with increases up to 5.0±2.45 hours reported after a 900 mg dose. With repeated administration, the half-life decreases and reaches average values of approximately 2 to 3 hours. The half-life does not differ in patients with renal failure at doses not exceeding 600 mg daily, and consequently, no dosage adjustment is required. The half-life of rifampin at a dose of 720 mg daily has not been established in patients with renal failure at doses not exceeding 600 mg daily, and consequently, no dosage adjustment is required. The half-life of rifampin at a dose of 720 mg daily has not been established in patients with renal failure at doses not exceeding 600 mg daily, and consequently, no dosage adjustment is required.

Rifampin is rapidly eliminated in the bile, and an enterohepatic circulation ensues. During this process, rifampin undergoes progressive deacetylation so that nearly all the drug in the bile is in this form in about 6 hours. This metabolite has antibacterial activity. Intestinal deacetylation is reduced by deacetylation, and elimination is facilitated. Up to 30% of a dose is excreted in the urine, with about half of this being unchanged drug.

Intravenous Administration
After intravenous administration of a 300 or 600 mg dose of rifampin infused over 30 minutes to healthy volunteers (n=12), mean peak plasma concentrations were 9.0±3.0 and 17.5±5.0 mcg/mL, respectively. Total body clearances after the 300 and 600 mg IV doses were 0.19±0.06 and 0.14±0.03 L/hr/kg, respectively. Volumes of distribution at steady state were 0.65±0.14 and 0.64±0.11 L/kg for the 300 and 600 mg IV doses, respectively. After intravenous administration of 300 or 600 mg doses, rifampin plasma concentrations in these volunteers remained detectable for 8 and 12 hours, respectively (see Table).

### Plasma Concentrations (mean ± standard deviation, mcg/mL)

<table>
<thead>
<tr>
<th>Rifampin Dose IV</th>
<th>30 min</th>
<th>1 hr</th>
<th>2 hr</th>
<th>4 hr</th>
<th>8 hr</th>
<th>12 hr</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 mg</td>
<td>8.9±2.9</td>
<td>4.9±1.3</td>
<td>4.0±1.3</td>
<td>2.5±1.0</td>
<td>1.1±0.6</td>
<td>&lt;0.4</td>
</tr>
<tr>
<td>600 mg</td>
<td>17.4±5.1</td>
<td>11.7±2.8</td>
<td>9.4±2.3</td>
<td>6.4±1.7</td>
<td>3.5±1.4</td>
<td>1.2±0.6</td>
</tr>
</tbody>
</table>

Plasma concentrations after the 600 mg dose, which were disproportionately higher (up to 30% greater than expected) than those found after the 300 mg dose, indicated that the elimination of larger doses was not as rapid. After repeated once-a-day infusions (3 hr duration) of 600 mg in patients (n=5) for 7 days, concentrations of IV rifampin decreased from 5.8±3.38 mcg/mL 8 hours after the infusion of 300 mg to 2.6±1.98 mcg/mL 8 hours after the infusion of 600 mg. Rifampin is widely distributed throughout the body. It is present in effective concentrations in many organs and body fluids, including cerebrospinal fluid.

### Microbiological Activity
Rifampin inhibits DNA-dependent RNA polymerase activity in susceptible Mycobacterium tuberculosis organisms. Specifically, it interacts with bacterial RNA polymerase but does not inhibit the mammalian enzyme.

### Drug Resistance
Rifampin resistance to rifampin are likely to be resistant to other rifamycins.

In the treatment of both tuberculosis and the meningococcal carrier state (see INDICATIONS AND USAGE), the small number of resistant cells present within large populations of susceptible cells can rapidly become predominant. In addition, resistance to rifampin has been determined to occur as single-step mutations of the M24-A) utilizes the BACTEC 460 machine to compare the growth in the control culture, indicates resistance.

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Interpretation

Zone Diameter (mm)

Rifampin is indicated in the treatment of all forms of tuberculosis. If the patient is not responding to therapy, the drug regimen should be modified. If susceptibility tests should be performed for establishment of the carrier state and the correct treatment. That the usefulness of rifampin in the treatment of asymptomatic meningococcal carriers is preserved, the drug should be used only when the risk of meningococcal disease is high. To reduce the development of drug-resistant bacteria and maintain the effectiveness of rifampin and other antibacterial drugs, rifampin should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

MIC (mcg/mL)

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>MIC (mcg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>ATCC 29213</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>ATCC 29212</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>ATCC 25922</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>ATCC 27853</td>
</tr>
<tr>
<td>Haemophilus influenzae</td>
<td>ATCC 49247</td>
</tr>
</tbody>
</table>

Diffusion Techniques

Quantitative methods that require measurement of zone diameters provide reproducible estimates of the susceptibility of bacteria to antimicrobial compounds. One such standardized procedure uses a standardized dilution method (broth, agar, or microdilution) or equivalent with rifampin powder. The MIC values obtained should be interpreted according to the following criteria for Neisseria meningitidis:

MIC (mcg/mL)

<table>
<thead>
<tr>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>≥4</td>
</tr>
<tr>
<td>(S) Susceptible</td>
</tr>
<tr>
<td>(I) Intermediate</td>
</tr>
<tr>
<td>(R) Resistant</td>
</tr>
</tbody>
</table>

A report of “susceptible” indicates that the pathogen is likely to be inhibited by usually achievable concentrations of the antimicrobial compound in the blood. A report of “intermediate” indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where the maximum acceptable dose of drug can be used. This category also provides a buffer zone that prevents small-uncontrolled technical factors from causing major discrepancies in interpretation. A report of “resistant” indicates that usually achievable concentrations of the antimicrobial compound in the blood are unlikely to be inhibitory and that other therapy should be selected. Measurement of MIC or minimum bactericidal concentrations (MBC) and achieved antimicrobial compound concentrations may be appropriate to guide therapy in some infections. (See CLINICAL PHARMACOLOGY section for further information on drug concentrations achieved in infected body sites and other pharmacokinetic properties of this antimicrobial drug product.) Standardized susceptibility test procedures require the use of laboratory control microorganisms. The use of these microorganisms does not imply clinical efficacy (see INDICATIONS AND USAGE); they are used to control the technical aspects of the laboratory procedures. Standard rifampin powder should give the following MIC values:

MIC (mcg/mL)

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>MIC (mcg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neisseria meningitidis</td>
<td>≤1</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>≥2</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>≥4</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>(S) Susceptible</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>(I) Intermediate</td>
</tr>
<tr>
<td>Neisseria meningitidis</td>
<td>(R) Resistant</td>
</tr>
</tbody>
</table>

Microorganism

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Zone Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. aureus</td>
<td>ATCC 29223</td>
</tr>
<tr>
<td>E. coli</td>
<td>ATCC 29222</td>
</tr>
<tr>
<td>H. influenzae</td>
<td>ATCC 49247</td>
</tr>
</tbody>
</table>

INDICATIONS AND USAGE

In the treatment of both tuberculosis and the meningococcal carrier state, the small number of resistant cells present within large populations of susceptible cells can rapidly become the predominant type. Bacteriologic cultures should be obtained before the start of therapy to confirm the susceptibility of the organism to rifampin and they should be repeated throughout therapy to monitor the response to treatment. Since resistance can emerge rapidly, susceptibility tests should be performed in the event of persistent positive cultures during the course of treatment. If test results show resistance to rifampin and the patient is not responding to therapy, the drug regimen should be modified. Tuberculosis

Rifampin is indicated in the treatment of all forms of tuberculosis. A three-drug regimen consisting of rifampin, isoniazid, and pyrazinamide (e.g., Rifater®) is recommended in the initial phase of short-course therapy which is usually continued for 2 months. The Advisory Council for the Elimination of Tuberculosis, the American Thoracic Society, and Centers for Disease Control and Prevention recommend that either streptomycin or ethambutol be added as a fourth drug in a regimen containing isoniazid (INH), rifampin, and pyrazinamide for the initial therapy of tuberculosis unless the likelihood of INH resistance is very low. The need for a fourth drug should be reassessed when the results of susceptibility testing are known. If community rates of INH resistance are currently less than 5% and an initial treatment regimen with fewer than four drugs may be considered. Following the initial phase, treatment should be continued with rifampin and isoniazid (e.g., RIFAMAT®) for at least 4 months. Treatment should be continued for longer if the patient is still sputum or culture positive, if resistant organisms are present, or if the patient is HIV positive.

RIFADIN IV is indicated for the initial treatment and retreatment of tuberculosis when the drug cannot be taken by mouth.

Meningococcal Carriers

Rifampin is indicated for the treatment of asymptomatic carriers of Neisseria meningitidis to eliminate meningococci from the nasopharynx. Rifampin is not indicated for the treatment of meningococcal infection because of the rapid emergence of resistant organisms. (See WARNINGS.)

General

Rifampin is contraindicated in patients who are also receiving ritonavir-boosted saquinavir due to an increased risk of severe hepatocellular toxicity. (See PRECAUTIONS, Drug Interactions.)

Rifampin is contraindicated in patients who are also receiving atazanavir, darunavir, fosamprenavir, saquinavir, or tipranavir due to the potential of rifampin to substantially decrease plasma concentrations of these antiviral drugs, which may result in loss of antiviral efficacy and/or development of viral resistance.

WARNINGS

Rifampin has been shown to produce liver dysfunction. Fatalities associated with jaundice have occurred in patients with liver disease and in patients taking rifampin with other hepatotoxic agents. Patients with impaired liver function should be given rifampin only in cases of necessity and then with caution and under strict medical supervision. In these patients, careful monitoring of liver function, especially SGPT/ALT and SGOTAST should be carried out prior to therapy and then every 2 to 4 weeks during therapy. If signs of hepatocellular damage occur, rifampin should be withdrawn. In some cases, hyperbilirubinemia resulting from competition between rifampin and bilirubin for excretory pathways of the liver at the cell level can occur in the early days of treatment. An isolated report showing a moderate rise in bilirubin and/or transaminase level is not in itself an indication for interrupting treatment; rather, the decision should be made after repeating the tests, noting trends in the levels, and considering them in conjunction with the patient's clinical condition.

Rifampin has enzyme-inducing properties, including induction of delta amino levulinic acid synthetase. Isolated reports have associated porphyria exacerbation with rifampin administration. The possibility of rapid emergence of resistant meningococci restricts the use of RIFADIN to short-term treatment of the asymptomatic meningococcal carrier state. RIFADIN is not to be used for the treatment of meningococcal disease. Systemic hypersensitivity reactions, including Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome, may occur in patients receiving RIFADIN (see ADVERSE REACTIONS). Signs and symptoms of hypersensitivity reactions may include fever, rash, urticaria, angioedema, hypotension, acute bronchospasm, conjunctivitis, thrombocytopenia, neutropenia, elevated liver transaminases or flu-like syndrome (weakness, fatigue, muscle pain, nausea, vomiting, headache, chills, achy, itchy, sweats, dizziness, shortness of breath, chest pain, cough, syncope, palpitations). These reactions may be severe and DRESS may be fatal. Manifestations of hypersensitivity, such as fever, lymphadenopathy or laboratory abnormalities (including eosinophilia, liver abnormalities) may be present even though rash is not evident. Monitor patients receiving RIFADIN for signs/symptoms of hypersensitivity reactions. If any signs or symptoms occur, discontinue RIFADIN and administer supportive measures.

PRECAUTIONS

General

RIFADIN should be used with caution in patients with a history of diabetes mellitus, as diabetes management may be more difficult.

Prescribing rifampin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the likelihood of drug resistance development.

For the treatment of tuberculosis, rifampin is usually administered on a daily basis. Doses of rifampin greater than 600 mg given once or twice weekly have resulted in a higher incidence of adverse reactions, including the "flu syndrome" (fever, chills and malaise), gastrointestinal reactions (nausea, abdominal pain, diarrhea, vomiting, anorexia), hepatic reactions, shortness of breath, shock, anaphylaxis, and renal failure. Recent studies indicate that regimens using twice-weekly doses of rifampin 600 mg plus isoniazid 15 mg/kg are much better tolerated.

Rifampin is not recommended for intermittent therapy; the patient should be cautioned against intentional or accidental interruption of the daily dosage regimen since rare renal hypersensitivity reactions have been reported when therapy was resumed in such cases. Rifampin has enzyme induction properties that can enhance the metabolism of endogenous substrates including adrenal hormones, thyroid hormones, and vitamin D. Rifampin
\textbf{Enzyme Induction} 

Rifampin is known to induce certain cytochrome P-450 enzymes. Administration of rifampin with drugs that undergo biotransformation through these metabolic pathways may accelerate elimination of coadministered drugs. To maintain optimum therapeutic blood levels, dosages of drugs metabolized by these enzymes may require adjustment when starting or stopping concomitantly administered rifampin.

Rifampin has been reported to substantially decrease the plasma concentrations of the following antiviral drugs: atazanavir, darunavir, fosamprenavir, saquinavir, and sparfuvir. These antiviral drugs must not be coadministered with rifampin. (See CONTRAINDICATIONS.)

\textbf{Drug Interactions} 

**Healthy subjects who received rifampin 600 mg once daily concomitantly with saquinavir 1000 mg/ritonavir 100 mg twice daily (ritonavir-boosted) saquinavir** developed severe hepatocellular toxicity. Therefore, concomitant use of these medications is contraindicated. (See CONTRAINDICATIONS.)

\textbf{Hematologic} 

Agranulocytosis has been reported very rarely. Rare reports of disseminated intravascular coagulation have been observed. Thrombocytopenia has occurred primarily with high dose intermittent therapy, but has also been observed in patients receiving rifampin and rifabutin concurrently. It is recommended that the prothrombin time be performed daily or as frequently as necessary to establish and maintain the required dose of anticoagulant.

Other Interactions 

When the two drugs were taken concomitantly, decreased concentrations of atovaquone and increased concentrations of rifampin were observed.

Concomitant administration may reduce the absorption of rifampin. Daily doses of rifampin should be given at least 1 hour before the ingestion of antacids.

Probenecid and cimetidine have been reported to increase the bioavailability of rifampin. Dosage adjustments should be made if indicated by the patient's clinical condition.

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When rifampin is given concomitantly with either halothane or isoniazid, the potential for hepatitis is increased. The concomitant use of rifampin and halothane should be avoided. Patients receiving both rifampin and isoniazid should be monitored close for hepatotoxicity.

\textbf{Drug/Laboratory Interactions} 

Plasma concentrations of sulfapyridine may be reduced following the concomitant administration of sulfasalazine and rifampin. This finding may be the result of alteration in the colonic bacteria responsible for the reduction of sulfasalazine to sulfapyridine and mesalamine.

**Carcinogenesis, Mutagenesis, Impairment of Fertility** 

Rifampin has been shown to have increased the incidence of tumor formation in rats and mice, but has not been evaluated in other species. Workers handling rifampin should avoid inhalation of the dust or vapors. 

\textbf{Laboratory Tests} 

Adults treated for tuberculosis with rifampin should have baseline measurements of hepatitis enzymes, bilirubin, serum creatinine, complete blood count, and a platelet count (or estimate). Baseline tests are unnecessary in pediatric patients unless a complicating condition is known or clinically suspected. Patients should be seen at least monthly during therapy and should be specifically questioned for symptoms associated with adverse reactions. All patients with abnormalities should have follow-up, including laboratory testing, if necessary. Routine laboratory monitoring for toxicity in people with normal baseline measurements is generally not necessary.
Preparation of Solution for IV Infusion
Reconstitute the lyophilized powder by transferring 10 mL of sterile water for injection to a vial containing 600 mg of rifampin for injection. Swirl vial gently to completely dissolve the antibiotic. The reconstituted solution contains 60 mg rifampin per mL and is stable at room temperature for up to 30 hours. Prior to administration, withdraw from the reconstituted solution a volume equivalent to the amount of rifampin calculated to be administered and add to 500 mL of infusion medium. Mix well and infuse at a rate allowing for complete infusion within 3 hours. Alternatively, the amount of rifampin calculated to be administered may be added to 100 mL of infusion medium and infused in 30 minutes.

If drug in dose form is 5% for injection (D5W) are stable at room temperature for up to 8 hours and should be prepared and used within this time. Precipitation of rifampin from the infusion solution may occur beyond this time. Dilutions in normal saline are stable at room temperature for up to 6 hours and should be prepared and used within this time. Other infusion solutions are not recommended.

Incompatibilities
Physical incompatibility (precipitate) was observed with undiluted (5% mg/mL) and diluted (1 mg/mL in normal saline) diilazem hydrochloride and rifampin (6 mg/mL in normal saline) during simulated Y-site administration.

Meningococcal Carriers
Adults: For adults, it is recommended that 600 mg rifampin be administered twice daily for two days.

Pediatric Patients: Pediatric patients 1 month of age or older: 10 mg/kg (not to exceed 600 mg per dose) every 12 hours for two days.

Pediatric patients under 1 month of age: 5 mg/kg every 12 hours for two days.

Preparation of Extemporaneous Oral Suspension
For pediatric and adult patients in whom capsule swallowing is difficult or where lower doses are needed, a liquid suspension may be prepared as follows:

RIFADIN 1% w/v suspension (10 mg/mL) can be compounded using one of four syrups—Simple Syrup (Syrup NF), Simple Syrup (Hucoro McConnell’s), Syl ena (Syrup Emerson Laboratories), or Ramifine Syrup (Hucoro Laboratories).
1. Empty the contents of four RIFADIN 300 mg capsules or eight RIFADIN 150 mg capsules onto a piece of weighing paper.
2. If necessary, gently crush the capsule contents with a spatula to produce a fine powder.
3. Transfer the rifampin powder blend to a 4-ounce amber glass or plastic (high density polyethylene [HDPE], polypropylene, or polycarbonate) prescription bottle.
4. Rinse the paper and spatula with 20 mL of one of the above-mentioned syrups, and add the rinse to the bottle. Shake vigorously.
5. Add 100 mL of syrup to the bottle and shake vigorously.

This compounding procedure results in a 1% w/v suspension containing 10 mg rifampin/mL. Stability studies indicate that the suspension is stable when stored at room temperature (25±3°C) or in a refrigerator (2–8°C) for four weeks. This extemporaneously prepared suspension must be shaken well prior to administration.

HOW SUPPLIED
150 mg maroon and scarlet capsules imprinted “RIFADIN 150.”
Bottles of 30 (NDC 0068-0510-30)
300 mg maroon and scarlet capsules imprinted “RIFADIN 300.”
Bottles of 60 (NDC 0068-0508-60)
Bottles of 100 (NDC 0068-0508-61)

Storage: Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature]. Keep tightly closed. Store in a dry place. Avoid excessive heat.

RIFADIN IV (rifampin for injection USP) is available in glass vials containing 600 mg rifampin (NDC 0068-0597-01).
Storage: Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature]. Avoid excessive heat (temperatures above 40°C or 104°F). Protect from light.

REFERENCES

Rifadin capsules are manufactured for:
sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
A SANOFI COMPANY

Rifadin IV (rifampin for injection USP) is manufactured by:
sanofi-aventis U.S. LLC
Bridgewater, NJ 08807
A SANOFI COMPANY

Rifadin IV (rifampin for injection USP) is manufactured by:
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Bridgewater, NJ 08807
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