



Rifampicin

Natricin® Forte

200mg/5mL Suspension
Anti-tuberculosis

FORMULATION:

Each 5mL Natricin Forte suspension contains:

Rifampicin.....200mg

INDICATIONS:

Tuberculosis in all forms, leprosy, infections caused by rifampicin- sensitive microorganisms e.g. *Staphylococci* and *Neisseria gonorrhoea*; asymptomatic carriers of *N. meningitidis*.

PHARMACODYNAMICS

Rifampicin is bactericidal against a wide range of microorganisms and interferes with their synthesis of nucleic acids by inhibiting deoxyribonucleic acid (DNA)- dependent ribonucleic acid (RNA) polymerase. It has the ability to kill intracellular organisms.

PHARMACOKINETICS

Rifampicin is readily absorbed from the gastrointestinal tract. Peak serum concentrations of the order of 10µg/ml occur about 2 to 4 hours after a dose of 10 mg/kg body weight on an empty stomach. Absorption of rifampicin is reduced when the drug is ingested with food. The pharmacokinetics (oral and intravenous) in children is similar to adults.

In normal subjects the biological half-life of rifampicin in serum averages about 3 hours after a 600 mg dose and increases to 5.1 hours after a 900 mg dose. With repeated administration, the half-life decreases and reaches average values of approximately 2-3 hours. At a dose of up to 600 mg/day, it does not differ in patients with renal failure and consequently, no dosage adjustment is required.

CONTRAINDICATIONS:

Presence of jaundice; history of hypersensitivity reaction to any of the rifampicins.
Severe liver damage.

WARNINGS:

Rifampicin has been shown to produce liver dysfunction. Since an increased risk may exist for individuals with liver disease, benefit must be weighed carefully against any risk of further liver damage. Periodic liver function monitoring is mandatory.

USAGE IN PREGNANCY:

Teratogenicity of rifampicin in humans has not been reported. However, rifampicin is reported to cross the placental barrier although effect of the substance on the human fetus is not known.

Before starting the treatment with Natricin, please inform your doctor if you are pregnant or expecting pregnancy. If possible, Natricin Forte should not be taken in the first 3 months of pregnancy.

The reliability of oral contraceptives may be affected by rifampicin. Alternative contraceptive measures may be considered.

ADVERSE EFFECTS:

Rifampicin is usually well tolerated. Adverse effects are common during intermittent therapy or after starting interrupted treatment.

Hypersensitivity reactions have been reported. Occasionally pruritus, rash, sore mouth and tongue, urticaria, and exudative conjunctivitis are manifested. Gastro-intestinal disturbances, fever and generalized numbness, allergic immunologic reactions are rare. Administration on an empty stomach is recommended for maximal absorption, but this has to be balanced against administration after a meal to minimize gastro-intestinal intolerance.

Natricin may cause reddish discoloration of body fluids, e.g. urine, saliva and lacrimal fluid. It may permanently discolor soft contact lenses.

Natricin Forte Suspension does not contain sodium metabisulfite.

INTERACTIONS:

The blood concentrations of methadone, oral hypoglycemia, digitalis derivatives, corticosteroids and anticoagulants may be affected if rifampicin is given simultaneously. Dosage adjustment is recommended in such case.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

DOSAGE AND ADMINISTRATION:

10 mg/kg body weight with a daily maximum dosage of 600mg or
15mg/kg body weight (maximum 900mg) two or three times daily.

Administer Natricin Forte Suspension on an empty stomach. It should be taken one hour before or two hours after a meal.

OVERDOSAGE

Do not take more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Natricin Forte Suspension, please go to the emergency department of the closest hospital or nursing home. Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. Please consult your physician or pharmacist for more information.

For suspected adverse drug reaction, report to the FDA: www.fda.gov

AVAILABILITY

200 mg/5 mL suspension - Bottles of 60mL, 120mL and 250mL

Registration Number: DR-XY23213

Date of First Authorization: Septmeber 2018

Revision Date: May 2018

SHAKE WELL THE SUSPENSION BEFORE USING

STORE AT TEMPERATURES NOT EXCEEDING 30°C

Manufactured for
Natrapharm, Inc.
The Patriot Building
Km 18, West Service Road,
SLEX, Sucat, Parafiaque City
by Lloyd Laboratories, Inc.
10 Lloyds Avenue,
First Bulacan Industrial City,
Malolos City, Bulacan

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