

RIFAMPICIN



FAMPISEC
200mg/5mL Suspension
ANTITUBERCULOSIS

FORMULATION:

Each 5 mL (one tear) (one full) contains:

Rifampicin..... 200 mg

DESCRIPTION:

Rifampicin belongs to the rifamycin group of antibiotics. It is used for the initial treatment of pulmonary tuberculosis in association with antituberculosis agents, especially ethambutol and isoniazid and in the elimination of meningococci from carriers. It has been also used in a variety of conditions caused by susceptible organisms especially leprosy and gonorrhoea. Rifampicin has been shown to be immunosuppressant.

FAMPISEC is a Brick Red to Red-brown viscous Suspension. In Strawberry Flavor. Box of 1's, Amber glass Bottle of 60 mL and 120 mL.

WHAT IS IN THE MEDICINE?

FAMPISEC Oral Suspension contains a medicine called rifampicin. It belongs to a group of medicines called anti-bacterials. It works by killing the bacteria that cause infections.

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STRENGTH OF THE MEDICINE?

See Formulation

WHAT IS THIS MEDICINE USED FOR?

For the treatment of pulmonary and extra pulmonary tuberculosis caused by typical (and some atypical) Mycobacterium tuberculosis, leprosy, including resistant strains infections caused by Gram-positive and Gram-negative and other sensitive microorganisms.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

10-20 mg/kg (not to exceed 600 mg) once daily. Should be given preferably on an empty stomach. Or as prescribed by the physician.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If: You are allergic (hypersensitive) to rifampicin or any of the other ingredients of the FampiSec Oral Suspension. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue. You have yellowing of the skin and eyes (jaundice). You are taking saquinavir or ritonavir for an HIV infection. It contains Sodium Metabisulfite which may cause allergic reaction in certain susceptible person.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Rifampicin should not be given to patients with jaundice and should be used with caution in other patients with impaired liver function, especially when given with isoniazid. It induces microsomal liver enzymes and has been reported to decrease the effects of corticosteroids, coumarin, anticoagulants, oral contraceptives and tolbutamide. Hypersensitivity reactions including nephrotoxicity appear to be associated with intermittent use of Rifampicin. A non-hormonal method of contraception is recommended during Rifampicin therapy, because of its potent effect. Rifampicin causes an orange-red discoloration of the urine and other body fluids. Soft contact lenses worn by patients receiving Rifampicin may become permanently stained.

UNDESIRABLE EFFECTS:

Rifampicin is usually well tolerated. The incidence of side-effects appears to be influenced by the schedule of administration. Gastrointestinal side-effects include nausea, vomiting, diarrhea and anorexia have sometimes been severe enough to necessitate withdrawal. Rifampicin produces abnormalities in the liver function; jaundice is usually associated with concomitant use of other drugs, especially isoniazid. Some patients may experience a febrile reaction with influenza like symptoms, alterations in the kidney function and renal failure have occurred and are considered to be due to hypersensitivity, skin rashes, urticaria, eosinophilia, leukopenia, thrombocytopenia, pupura and has haemolysis have been reported. Other side effects include confusion, drowsiness, weakness, ataxia, dizziness, peripheral neuropathy, blurred vision, transient hearing loss and menstrual irregularities. Rifampicin is usually well tolerated. Advance effects are more common during intermittent therapy or after restarting interrupted treatment. Some patients may experience a cutaneous syndrome which present to 2 to 3 hours after a daily or intermittent dose as facial flushing, itching, rash or rarely eye irritation. A 12-hour flue syndrome of fever, chill, bone pain, shortness of breath, and malaise has been associated with intermittent administration. It usually occurs 3 to 6 months of intermittent treatment as has a higher incidence with doses of 20 mg or more per kg body-weight given once a weekly.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING FAMPISEC?

Avoid foods that are high in tyramine or histamine, listed below. Tyramine or histamine can interact with this medication and cause unpleasant side effects. These foods include: beer or wine (especially red wine);

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for the forgotten dose.

SIGNS AND SYMPTOMS OF OVERDOSE

Overdose can cause worsening symptoms such as nausea, vomiting, stomach pain, itching, headache, lack of energy leading to loss of consciousness, and dark or discolored skin, saliva, tears, urine, or stools

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor or contact a Poison Control Center right away

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at Temperatures not exceeding 30°C

ADR REPORTING STATEMENT:

For suspected adverse drug reaction, report to FDA: www.fda.gov/ph Patient must seek medical attention immediately at the first sign of any adverse drug reactions.

AVAILABILITY AND SUPPLY:

Boston Round Amber Bottle of 60 mL and 120 mL

REGISTRATION NO.: DRP-1309

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION:

21 October 2005

DATE OF REVISION OF PATIENT INFORMATION LEAFLET:

01 September 2020



Manufactured by:

SAN MARINO Laboratories CORP.
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