

Rifactine suspension

Rifampicin 2% (100 mg/5 ml)

1. Name of the medicinal product
Rifactine suspension 2% (100 mg/5 ml).

2. Qualitative and quantitative composition

Rifampicin 2% (100 mg/5 ml).

3. Pharmaceutical form

Oral suspension

4. Clinical particulars

Indications for use

Tuberculosis: In combination with other active anti-tuberculosis drugs in the treatment of all forms of tuberculosis, including fresh, advanced, chronic and drug-resistant cases, Rifactine is also effective against most atypical strains of Mycobacteria.

Leprosy: In combination with at least one other active anti-leprosy drug in the management of multi bacillary and paucibacillary leprosy to effect conversion of the infectious state to a non-infectious state.

Other conditions: Leprosy, Leprosomy Disease, and serious tuberculous infections. To prevent emergence of resistant strains of the infecting organism, Rifactine should be used in combination with another antibiotic appropriate for the infection.

Prophylaxis of meningococcal meningitis: For the treatment of asymptomatic carriers of meningococcal meningitis from the nasopharynx.

Hæmophilus influenzae: For the treatment of asymptomatic carriers of Hæmophilus influenzae.

Method of administration

Oral suspension

For oral administration

The daily dose of Rifactine, from the patient's body weight, should preferably be taken at least 30 minutes before a meal or 2 hours after a meal to ensure rapid and complete absorption.

Tablets

Rifactine should be given with other effective anti-tuberculosis drugs to prevent the possible emergence of rifampicin-resistant strains of Mycobacteria.

Acute: The recommended single daily dose in tuberculosis is 8 - 12 mg/kg.

Usual: 10 mg/kg.

Patients weighing 50 kg or more: 500 mg.

Children: In children, oral doses of 10 - 20 mg / kg body weight daily are recommended, although a total daily dose should not usually exceed 600 mg.

Leprosy:

600 mg daily dose of rifampicin should be given once per month. Alternatively, a daily regimen may be used. The recommended single daily dose is 10 mg/kg.

Usual daily dose: Patients weighing less than 50 kg: 450 mg.

Patients weighing 50 kg or more: 600 mg.

In combination with other drugs should always be used in conjunction with at least one other anti-leprosy drug.

Bruceal Leprosy, Leprosomy Disease or serious staphylococcal infections

Adults: The recommended daily dose is 600-1200 mg given in 2 to 4 divided doses, together with an appropriate antibiotic to prevent the emergence of resistance during the infectious period.

Prophylaxis of Meningococcal Meningitis:

Adults: 600 mg twice daily for 2 days.

Children (1 - 12 years): 10 mg/kg twice daily for 2 days.

Usual: 10 mg/kg twice daily for 2 days.

Prophylaxis of Hæmophilus influenzae

Adults and children: For members of households exposed to H. influenzae B disease when the household contains a child 4 years of age or younger, it is recommended that the child should receive rifampicin 20 mg / kg orally daily (maximum dose 600 mg) for 4 days.

Index case should be treated prior to discharge from hospital.

Neonates (1 month): 10 mg/kg for 4 days.

Impaired liver function:

A usual dose of 8 mg/kg should not exceed in patients with impaired liver function.

Use in the elderly:

In elderly, the renal excretion of rifampicin is decreased principally with physiological decrease of renal function due to concomitant increase of liver enzymes, the terminal half-life in serum is similar to that of younger patients.

However, as increased blood levels have been noted in one study of rifampicin in elderly patients, caution should be exercised in using rifampicin in such patients, especially if there is evidence of impaired liver function.

Contraindications:

Rifactine is contraindicated in the presence of jaundice, and in patients who are hypersensitive to the rifamycins or any of the excipients.

Rifactine use is contraindicated when given concomitantly with the combination of quinupristin/dalfopristin.

Special warnings and precautions for use:

Rifampicin should be given under the supervision of a respiratory or other suitable qualified physician.

Cautions should be taken in case of renal impairment if dose > 300 mg/day.

All individuals should have pre-treatment measurement of liver function.

Adults treated for tuberculosis with rifampicin should have baseline measurements of hepatic enzymes, bilirubin, serum creatinine, a complete blood count, and a platelet count (or estimate).

Breast feeding: Caution in pregnancy in children unless a complicating condition is known or clinically suspected.

Patients with impaired liver function should only be given rifampicin in cases of necessity, and then with caution and under close medical supervision. In these patients, high doses of rifampicin are reduced and careful monitoring of liver function, particularly serum transaminase (ALT) and serum aspartate aminotransferase (AST) should initially be carried out prior to therapy. Therapy for weeks to every two weeks for the next six weeks. If signs of hepatotoxic damage occur, rifampicin should be withdrawn immediately. Transient elevation of BSP and serum bilirubin has been reported. Rifampicin may impair biliary excretion of contrast media used for visualisation of gallbladder, due to competition for biliary excretion. Therefore, these tests should be performed before the morning dose of rifampicin.

Pregnancy and lactation:

Pregnant women: At high doses in animal rifampicin has been shown to have teratogenic effects. There are no well controlled studies with rifampicin in pregnant women.

Although rifampicin has been reported to cross the placental barrier and appear in cord blood, the effect of rifampicin, alone or in combination with other antibiotics, on the fetus is not known. Therefore, rifampicin should be avoided in pregnant women, especially if they are between 2 years of age, caution is particularly recommended when instituting therapeutic regimens in which rifampicin is used as concurrently with rifactine. If the patient has no evidence of pre-existing liver disease or any significant changes in hepatic function, rifampicin should only be repeated if fever, vomiting, jaundice or other deterioration in the patient occurs.

Patients should be seen at least monthly during the first few weeks of therapy.

Because of the possibility of immunological reaction including anaphylaxis (see

Undesirable effects) occurring with intermittent therapy (less than 2 to 3 times per week) patients should be closely monitored. Patients should be cautioned against interrupting therapy.

Rifampicin has some enzyme induction properties that can enhance the metabolism of endogenous substrates, inducing adrenal hormones, thyroid hormones and vitamin D. Isolated reports have associated porphyria exacerbation with rifampicin administration.

Rifampicin contains certain metallo-urides which may cause allergic type reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible people. Rifampicin may cause redilation colour of urine, sweat, sputum and tears, and the patient should be informed of this. Soft contact lenses have been permitted to remain in situ (unless unclean).

Rifactine should be discontinued if this, Soft contact lenses have been permitted to remain in situ (unless unclean).

All patients with abnormalities should have follow up examinations, including laboratory testing, if necessary.

Rifactine should be taken into account in patients with diabetes mellitus. May also be harmful to teeth.

Patients with rare glucose-galactose malabsorption should not take this medicine.

Interaction with other medicines and other forms of interaction

Rifampicin will induce cytochrome P-450 enzymes and the metabolism of many other drugs.

Rifampicin is an inducer of cytochrome P-450 enzymes.

Rifampicin is an inducer of CYP 2D6, CYP 2C19, CYP 2C9, CYP 2B6, CYP 3A4, CYP 2E1, CYP 2J2, CYP 2C8, CYP 2C7, CYP 2C6, CYP 2C4, CYP 2C3, CYP 2C2, CYP 2B7, CYP 2B6, CYP 2B4, CYP 2B3, CYP 2B2, CYP 2A6, CYP 2A1, CYP 2A2, CYP 2A3, CYP 2A4, CYP 2A5, CYP 2A7, CYP 2A8, CYP 2A9, CYP 2A10, CYP 2A11, CYP 2A12, CYP 2A13, CYP 2A14, CYP 2A15, CYP 2A16, CYP 2A17, CYP 2A18, CYP 2A19, CYP 2A20, CYP 2A21, CYP 2A22, CYP 2A23, CYP 2A24, CYP 2A25, CYP 2A26, CYP 2A27, CYP 2A28, CYP 2A29, CYP 2A30, CYP 2A31, CYP 2A32, CYP 2A33, CYP 2A34, CYP 2A35, CYP 2A36, CYP 2A37, CYP 2A38, CYP 2A39, CYP 2A40, CYP 2A41, CYP 2A42, CYP 2A43, CYP 2A44, CYP 2A45, CYP 2A46, CYP 2A47, CYP 2A48, CYP 2A49, CYP 2A50, CYP 2A51, CYP 2A52, CYP 2A53, CYP 2A54, CYP 2A55, CYP 2A56, CYP 2A57, CYP 2A58, CYP 2A59, CYP 2A60, CYP 2A61, CYP 2A62, CYP 2A63, CYP 2A64, CYP 2A65, CYP 2A66, CYP 2A67, CYP 2A68, CYP 2A69, CYP 2A70, CYP 2A71, CYP 2A72, CYP 2A73, CYP 2A74, CYP 2A75, CYP 2A76, CYP 2A77, CYP 2A78, CYP 2A79, CYP 2A80, CYP 2A81, CYP 2A82, CYP 2A83, CYP 2A84, CYP 2A85, CYP 2A86, CYP 2A87, CYP 2A88, CYP 2A89, CYP 2A90, CYP 2A91, CYP 2A92, CYP 2A93, CYP 2A94, CYP 2A95, CYP 2A96, CYP 2A97, CYP 2A98, CYP 2A99, CYP 2A100, CYP 2A101, CYP 2A102, CYP 2A103, CYP 2A104, CYP 2A105, CYP 2A106, CYP 2A107, CYP 2A108, CYP 2A109, CYP 2A110, CYP 2A111, CYP 2A112, CYP 2A113, CYP 2A114, CYP 2A115, CYP 2A116, CYP 2A117, CYP 2A118, CYP 2A119, CYP 2A120, CYP 2A121, CYP 2A122, CYP 2A123, CYP 2A124, CYP 2A125, CYP 2A126, CYP 2A127, CYP 2A128, CYP 2A129, CYP 2A130, CYP 2A131, CYP 2A132, CYP 2A133, CYP 2A134, CYP 2A135, CYP 2A136, CYP 2A137, CYP 2A138, CYP 2A139, CYP 2A140, CYP 2A141, CYP 2A142, CYP 2A143, CYP 2A144, CYP 2A145, CYP 2A146, CYP 2A147, CYP 2A148, CYP 2A149, CYP 2A150, CYP 2A151, CYP 2A152, CYP 2A153, CYP 2A154, CYP 2A155, CYP 2A156, CYP 2A157, CYP 2A158, CYP 2A159, CYP 2A160, CYP 2A161, CYP 2A162, CYP 2A163, CYP 2A164, CYP 2A165, CYP 2A166, CYP 2A167, CYP 2A168, CYP 2A169, CYP 2A170, CYP 2A171, CYP 2A172, CYP 2A173, CYP 2A174, CYP 2A175, CYP 2A176, CYP 2A177, CYP 2A178, CYP 2A179, CYP 2A180, CYP 2A181, CYP 2A182, CYP 2A183, CYP 2A184, CYP 2A185, CYP 2A186, CYP 2A187, CYP 2A188, CYP 2A189, CYP 2A190, CYP 2A191, CYP 2A192, CYP 2A193, CYP 2A194, CYP 2A195, CYP 2A196, CYP 2A197, CYP 2A198, CYP 2A199, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A231, CYP 2A232, CYP 2A233, CYP 2A234, CYP 2A235, CYP 2A236, CYP 2A237, CYP 2A238, CYP 2A239, CYP 2A240, CYP 2A241, CYP 2A242, CYP 2A243, CYP 2A244, CYP 2A245, CYP 2A246, CYP 2A247, CYP 2A248, CYP 2A249, CYP 2A250, CYP 2A251, CYP 2A252, CYP 2A253, CYP 2A254, CYP 2A255, CYP 2A256, CYP 2A257, CYP 2A258, CYP 2A259, CYP 2A260, CYP 2A261, CYP 2A262, CYP 2A263, CYP 2A264, CYP 2A265, CYP 2A266, CYP 2A267, CYP 2A268, CYP 2A269, CYP 2A270, CYP 2A271, CYP 2A272, CYP 2A273, CYP 2A274, CYP 2A275, CYP 2A276, CYP 2A277, CYP 2A278, CYP 2A279, CYP 2A280, CYP 2A281, CYP 2A282, CYP 2A283, CYP 2A284, CYP 2A285, CYP 2A286, CYP 2A287, CYP 2A288, CYP 2A289, CYP 2A290, CYP 2A291, CYP 2A292, CYP 2A293, CYP 2A294, CYP 2A295, CYP 2A296, CYP 2A297, CYP 2A298, CYP 2A299, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A231, CYP 2A232, CYP 2A233, CYP 2A234, CYP 2A235, CYP 2A236, CYP 2A237, CYP 2A238, CYP 2A239, CYP 2A240, CYP 2A241, CYP 2A242, CYP 2A243, CYP 2A244, CYP 2A245, CYP 2A246, CYP 2A247, CYP 2A248, CYP 2A249, CYP 2A250, CYP 2A251, CYP 2A252, CYP 2A253, CYP 2A254, CYP 2A255, CYP 2A256, CYP 2A257, CYP 2A258, CYP 2A259, CYP 2A260, CYP 2A261, CYP 2A262, CYP 2A263, CYP 2A264, CYP 2A265, CYP 2A266, CYP 2A267, CYP 2A268, CYP 2A269, CYP 2A270, CYP 2A271, CYP 2A272, CYP 2A273, CYP 2A274, CYP 2A275, CYP 2A276, CYP 2A277, CYP 2A278, CYP 2A279, CYP 2A280, CYP 2A281, CYP 2A282, CYP 2A283, CYP 2A284, CYP 2A285, CYP 2A286, CYP 2A287, CYP 2A288, CYP 2A289, CYP 2A290, CYP 2A291, CYP 2A292, CYP 2A293, CYP 2A294, CYP 2A295, CYP 2A296, CYP 2A297, CYP 2A298, CYP 2A299, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A231, CYP 2A232, CYP 2A233, CYP 2A234, CYP 2A235, CYP 2A236, CYP 2A237, CYP 2A238, CYP 2A239, CYP 2A240, CYP 2A241, CYP 2A242, CYP 2A243, CYP 2A244, CYP 2A245, CYP 2A246, CYP 2A247, CYP 2A248, CYP 2A249, CYP 2A250, CYP 2A251, CYP 2A252, CYP 2A253, CYP 2A254, CYP 2A255, CYP 2A256, CYP 2A257, CYP 2A258, CYP 2A259, CYP 2A260, CYP 2A261, CYP 2A262, CYP 2A263, CYP 2A264, CYP 2A265, CYP 2A266, CYP 2A267, CYP 2A268, CYP 2A269, CYP 2A270, CYP 2A271, CYP 2A272, CYP 2A273, CYP 2A274, CYP 2A275, CYP 2A276, CYP 2A277, CYP 2A278, CYP 2A279, CYP 2A280, CYP 2A281, CYP 2A282, CYP 2A283, CYP 2A284, CYP 2A285, CYP 2A286, CYP 2A287, CYP 2A288, CYP 2A289, CYP 2A290, CYP 2A291, CYP 2A292, CYP 2A293, CYP 2A294, CYP 2A295, CYP 2A296, CYP 2A297, CYP 2A298, CYP 2A299, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A231, CYP 2A232, CYP 2A233, CYP 2A234, CYP 2A235, CYP 2A236, CYP 2A237, CYP 2A238, CYP 2A239, CYP 2A240, CYP 2A241, CYP 2A242, CYP 2A243, CYP 2A244, CYP 2A245, CYP 2A246, CYP 2A247, CYP 2A248, CYP 2A249, CYP 2A250, CYP 2A251, CYP 2A252, CYP 2A253, CYP 2A254, CYP 2A255, CYP 2A256, CYP 2A257, CYP 2A258, CYP 2A259, CYP 2A260, CYP 2A261, CYP 2A262, CYP 2A263, CYP 2A264, CYP 2A265, CYP 2A266, CYP 2A267, CYP 2A268, CYP 2A269, CYP 2A270, CYP 2A271, CYP 2A272, CYP 2A273, CYP 2A274, CYP 2A275, CYP 2A276, CYP 2A277, CYP 2A278, CYP 2A279, CYP 2A280, CYP 2A281, CYP 2A282, CYP 2A283, CYP 2A284, CYP 2A285, CYP 2A286, CYP 2A287, CYP 2A288, CYP 2A289, CYP 2A290, CYP 2A291, CYP 2A292, CYP 2A293, CYP 2A294, CYP 2A295, CYP 2A296, CYP 2A297, CYP 2A298, CYP 2A299, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A231, CYP 2A232, CYP 2A233, CYP 2A234, CYP 2A235, CYP 2A236, CYP 2A237, CYP 2A238, CYP 2A239, CYP 2A240, CYP 2A241, CYP 2A242, CYP 2A243, CYP 2A244, CYP 2A245, CYP 2A246, CYP 2A247, CYP 2A248, CYP 2A249, CYP 2A250, CYP 2A251, CYP 2A252, CYP 2A253, CYP 2A254, CYP 2A255, CYP 2A256, CYP 2A257, CYP 2A258, CYP 2A259, CYP 2A260, CYP 2A261, CYP 2A262, CYP 2A263, CYP 2A264, CYP 2A265, CYP 2A266, CYP 2A267, CYP 2A268, CYP 2A269, CYP 2A270, CYP 2A271, CYP 2A272, CYP 2A273, CYP 2A274, CYP 2A275, CYP 2A276, CYP 2A277, CYP 2A278, CYP 2A279, CYP 2A280, CYP 2A281, CYP 2A282, CYP 2A283, CYP 2A284, CYP 2A285, CYP 2A286, CYP 2A287, CYP 2A288, CYP 2A289, CYP 2A290, CYP 2A291, CYP 2A292, CYP 2A293, CYP 2A294, CYP 2A295, CYP 2A296, CYP 2A297, CYP 2A298, CYP 2A299, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A231, CYP 2A232, CYP 2A233, CYP 2A234, CYP 2A235, CYP 2A236, CYP 2A237, CYP 2A238, CYP 2A239, CYP 2A240, CYP 2A241, CYP 2A242, CYP 2A243, CYP 2A244, CYP 2A245, CYP 2A246, CYP 2A247, CYP 2A248, CYP 2A249, CYP 2A250, CYP 2A251, CYP 2A252, CYP 2A253, CYP 2A254, CYP 2A255, CYP 2A256, CYP 2A257, CYP 2A258, CYP 2A259, CYP 2A260, CYP 2A261, CYP 2A262, CYP 2A263, CYP 2A264, CYP 2A265, CYP 2A266, CYP 2A267, CYP 2A268, CYP 2A269, CYP 2A270, CYP 2A271, CYP 2A272, CYP 2A273, CYP 2A274, CYP 2A275, CYP 2A276, CYP 2A277, CYP 2A278, CYP 2A279, CYP 2A280, CYP 2A281, CYP 2A282, CYP 2A283, CYP 2A284, CYP 2A285, CYP 2A286, CYP 2A287, CYP 2A288, CYP 2A289, CYP 2A290, CYP 2A291, CYP 2A292, CYP 2A293, CYP 2A294, CYP 2A295, CYP 2A296, CYP 2A297, CYP 2A298, CYP 2A299, CYP 2A200, CYP 2A201, CYP 2A202, CYP 2A203, CYP 2A204, CYP 2A205, CYP 2A206, CYP 2A207, CYP 2A208, CYP 2A209, CYP 2A210, CYP 2A211, CYP 2A212, CYP 2A213, CYP 2A214, CYP 2A215, CYP 2A216, CYP 2A217, CYP 2A218, CYP 2A219, CYP 2A220, CYP 2A221, CYP 2A222, CYP 2A223, CYP 2A224, CYP 2A225, CYP 2A226, CYP 2A227, CYP 2A228, CYP 2A229, CYP 2A230, CYP 2A23

