SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Rifadin 100mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance (per 5ml dose)

Rifampicin 100 mg

Excipient with known effect (per 5ml dose)

Methyl-p-hydroxybenzoate (E218)	6.0 mg
Propyl-p-hydroxybenzoate (E216)	1.5 mg
Tween 80 (Polysorbate 80)	0.75 mg
Sucrose	2000 mg
Sodium metabisulphite (E223)	5.00 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Raspberry coloured and flavoured suspension.

4.1 Therapeutic indications

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. Rifadin 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 multibacillary and paucibacillary leprosy to effect conversion of the infectious state to a non-infectious state.

Other Infections: In the treatment of Brucellosis, Legionnaires Disease, and serious staphylococcal infections. To prevent emergence of resistant strains of the infecting organisms, Rifadin should be used in combination with another antibiotic appropriate for the infection.

Prophylaxis of meningococcal meningitis: For the treatment of asymptomatic carriers of N. meningitidis to eliminate meningococci from the nasopharynx. Haemophilus influenzae: For the treatment of asymptomatic carriers of H.influenzae and as chemoprophylaxis of exposed children, 4 years of age or younger.

4.2. Posology and method of administration

Recommended Dosage

For oral administration

The daily dose of Rifadin, calculated 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.

Tuberculosis:

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

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

Usual daily dose: Patients weighing less than 50 kg - 450 mg. Patients weighing 50 kg or more - 600 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 doses 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 the treatment of leprosy, rifampicin should always be used in conjunction with at least one other antileprosy drug,

Brucellosis, Legionnaires Disease or serious staphylococcal infections

Adults: The recommended daily dose is 600-1200 mg given in 2 to 4 divided doses, together with another appropriate antibiotic to prevent the emergence of resistant strains of the infecting organisms.

Prophylaxis of meningococcal meningitis

Adults: 600 mg twice daily for 2 days.

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

Children (3 months - 1 year): 5 mg/kg twice daily for 2 days.

Prophylaxis of Haemophilus 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 all members (including the child) receive rifampicin 20 mg/kg once daily (maximum daily dose 600 mg) for 4 days.
Index cases should be treated prior to discharge from hospital.

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

Impaired liver function:

A daily dose of 8 mg/kg should not be exceeded in patients with impaired liver function.

Use in the elderly:

In elderly patients, the renal excretion of rifampicin is decreased proportionally with physiological decrease of renal function; due to compensatory increase of liver excretion, 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.

4.3. Contraindications

Rifadin is contra-indicated in the presence of jaundice, and in patients who are hypersensitive to the rifamycins or any of the excipients.

Rifadin use is contraindicated when given concurrently with the combination of saquinavir/ritonavir (see section 4.5 Interactions).

4.4 Special warnings and precautions for use

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

Cautions should be taken in case of renal impairment if dose > 600 mg/day.

All tuberculosis patients should have pre-treatment measurements 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).
Baseline tests are unnecessary 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, lower doses of rifampicin are recommended and careful monitoring of liver function, especially serum alanine aminotransferase (ALT) and serum aspartate aminotransferase (AST) should initially be carried out prior to therapy, weekly for two weeks, then every two weeks for the next six weeks. If signs of hepatocellular damage occur, rifampicin should be withdrawn.

Rifampicin should also be withdrawn if clinically significant changes in hepatic function occur. The need for other forms of antituberculosis therapy and a different regimen should be considered. Urgent advice should be obtained from a specialist in the management of tuberculosis. If rifampicin is re-introduced after liver function has returned to normal, liver function should be monitored daily.

In patients with impaired liver function, elderly patients, malnourished patients, and possibly, children under two years of age, caution is particularly recommended when instituting therapeutic regimens in which isoniazid is to be used concurrently with Rifadin. If the patient has no evidence of pre-existing liver disease and normal pre-treatment liver function, liver function tests need only be repeated if fever, vomiting, jaundice or other deterioration in the patient's condition occur.

Patients should be seen at least monthly during therapy and should be specifically questioned concerning symptoms associated with adverse reactions.

In some patients hyperbilirubinaemia can occur in the early days of treatment. This results from competition between rifampicin and bilirubin for hepatic excretion.

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.

Because of the possibility of immunological reaction including anaphylaxis (see section 4.8 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 treatment.

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

Severe, systemic hypersensitivity reactions, including fatal cases, such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) syndrome have been observed during treatment with anti-tuberculosis therapy (See section 4.8).

Rifadin Oral Suspension should be discontinued if an alternative etiology for the signs and symptoms cannot be established.

Severe cutaneous adverse reactions (SCARs) including Steven-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported with a not known frequency in association with Rifadin Oral Suspension treatment.

Paradoxical drug reaction
After initial improvement of tuberculosis under therapy with Rifadin Oral Suspension, the symptoms may worsen again. In affected patients, clinical or radiological deterioration of existing tuberculous lesions or the development of new lesions have been detected. Such reactions have been observed within the first few weeks or months of initiation of tuberculosis therapy. Cultures are usually negative, and such reactions do not usually indicate treatment failure.

The cause of this paradoxical reaction is still unclear, but an exaggerated immune reaction is suspected as a possible cause. In case a paradoxical reaction is suspected, symptomatic therapy to suppress the exaggerated immune reaction should be initiated if necessary. Furthermore, continuation of the planned tuberculosis combination therapy is recommended.

Patients should be advised to seek medical advice immediately if their symptoms worsen. The symptoms that occur are usually specific to the affected tissues. Possible general symptoms include cough, fever, tiredness, breathlessness, headache, loss of appetite, weight loss or weakness (see section 4.8).

At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions.

It is important to note that early manifestations of hypersensitivity, such as fever, lymphadenopathy or biological abnormalities (including eosinophilia, liver abnormalities) may be present even though rash is not evident. If such signs or symptoms are present, the patient should be advised to consult immediately their physician.

If signs and symptoms suggestive of these reactions appear, Rifadin Oral Suspension should be withdrawn immediately and an alternative treatment considered (as appropriate).

Most of these reactions occurred within 2 days to 2 months after treatment initiation; the time to onset can vary depending on the conditions.

Rifadin Oral Suspension contains sodium metabisulfite which may cause allergic type reactions including anaphylactic symptoms and life threatening or less severe asthmatic episodes in certain susceptible people.

The suspension contains 2 g of sucrose per 5 ml dose. This should be taken into account in patients with diabetes mellitus. This may also be harmful to teeth. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Rifadin Oral Suspension contains 7.2mg of sodium (0.24mg/ml) per 600 mg daily dose and is essentially ‘sodium-free’.

Rifadin Oral Suspension contains Methyl-p-hydroxybenozoate and propyl-p-hydroxybenzoate, these may cause allergic reactions (possibly delayed).

This medicine contains potassium, less than 1 mmol (10.4mg) per 30ml dose, i.e. is essentially 'potassium free'.

Rifadin Oral Suspension may produce a discoloration (yellow, orange, red, brown) of the teeth, urine, sweat, sputum and tears, and the patient should be forewarned of this. Soft contact lenses have been permanently stained (see section 4.8).

Rifadin Oral Suspension is a well characterized and potent inducer of drug metabolizing enzymes and transporters and might therefore decrease or increase concomitant drug exposure, safety and efficacy (see Section 4.5). Therefore, potential drug interactions should be considered whenever beginning or discontinuing rifampicin treatment.

Rifampicin may cause vitamin K dependent coagulopathy and severe bleeding (see Section 4.8). Monitoring of occurrence of coagulopathy is recommended for patients at particular bleeding risk. Supplemental vitamin K administration should be considered when appropriate (vitamin K deficiency, hypoprothrombinemia).

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

4.5 Interaction with other medicinal products and other forms of interaction

Pharmacodynamic Interactions

When rifampicin is given concomitantly with the combination saquinavir/ritonavir, the potential for hepatotoxicity is increased. Therefore, concomitant use of Rifadin with saquinvir/ritonavir is contraindicated (see section 4.3 Contraindications).

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

The concomitant use of rifampicin with other antibiotics causing vitamin K dependent coagulopathy such as cefazolin (or other cephalosporins with N-methyl-thiotetrazole side chain) should be avoided as it may lead to severe coagulation disorders, which may result in fatal outcome (especially in high doses).

Effect of Rifadin Oral Suspension on other medicinal products

Induction of Drug Metabolizing Enzymes and Transporters
Rifadin Oral Suspension is a well characterized and potent inducer of drug metabolizing enzymes and transporters. Enzymes and transporters reported to be affected by Rifadin Oral Suspension include cytochromes P450 (CYP) 1A2, 2B6, 2C8, 2C9, 2C19, and 3A4, UDP-glucuronyltransferases (UGT), sulfotransferases, carboxylesterases, and transporters including P-glycoprotein (P-gp) and multidrug resistance-associated protein 2 (MRP2). Most drugs are substrates for one or more of these enzyme or transporter pathways, and these pathways may be induced by Rifadin Oral Suspension simultaneously. Therefore, Rifadin Oral Suspension may accelerate the metabolism and decrease the activity of certain co-administered drugs, or increase the activity of a coadministered pro-drug (where metabolic activation is required) and has the potential to perpetuate clinically important drug-drug interactions against

many drugs and across many drug classes (Table 1). To maintain optimum therapeutic blood levels, dosages of drugs may require adjustment when starting or stopping concomitantly administered Rifadin Oral Suspension.

Examples of drugs or drug classes affected by rifampicin:

- Antiarrhythmics (e.g. disopyramide, mexiletine, quinidine, propafenone, tocainide),
- Antiepileptics (e.g. phenytoin),
- Hormone antagonist (antiestrogens e.g. tamoxifen, toremifene, gestinone),
- Antipsychotics (e.g. haloperidol, aripiprazole),
- Anticoagulants (e.g. coumarins),
- Antifungals (e.g. fluconazole, itraconazole, ketoconazole, voriconazole),
- Antivirals (e.g. saquinavir, indinavir, efavirenz, amprenavir, nelfinavir, atazanavir, lopinavir, nevirapine),
- Barbiturates
- Beta-blockers (e.g. bisoprolol, propanolol),
- Anxiolytics and hypnotics (e.g. diazepam, benzodiazepines, zolpicolone, zolpidem),
- Calcium channel blockers (e.g. diltiazem, nifedipine, verapamil, nimodipine, isradipine, nicardipine, nisoldipine),
- Antibacterials (e.g. chloramphenicol, clarithromycin, dapsone, doxycycline, fluoroquinolones, telithromycin),
- Corticosteroids
- Cardiac glycosides (digitoxin, digoxin),
- Clofibrate,
- Systemic hormonal contraceptives including estrogens and progestogens,
- Antidiabetic (e.g. chlorpropamide, tolbutamide, sulfonylureas, rosiglitazone),
- Immunosuppressive agents (e.g. ciclosporin, sirolimus, tacrolimus)
- Irinotecan,
- Thyroid hormone (e.g. levothyroxine),
- Losartan,
- Analgestics (e.g. methadone, narcotic analgesics),
- Praziquantel,
- Quinine,
- Riluzole,
- Selective 5-HT3 receptor antagonists (e.g. ondansetron)
- Statins metabolised by CYP 3A4 (e.g. simvastatin),
- Theophylline,
- Tricyclic antidepressants (e.g. amitriptyline, nortriptyline),
- Cytotoxics (e.g. imatinib),
- Diuretics (e.g. eplerenone)
- Enalapril: decrease enalapril active metabolite exposure. Dosage adjustments should be made if indicated by the patient’s clinical condition
- Hepatitis-C antiviral drugs (eg, daclatasvir, simeprevir, sofosbuvir, telaprevir): Concurrent use of treatment of hepatitis-C antiviral drugs and rifampicin should be avoided.
- Morphine: Plasma concentrations of morphine may be reduced by rifampicin. The analgesic effect of morphine should be monitored and doses of rifampicin adjusted during and after treatment with rifampicin.
- Clopidogrel: Increases active metabolite exposure. Rifadin strongly induces CYP2C19, resulting in both an increased level of clopidogrel active metabolite and platelet inhibition, which in particular might potentiate the

risk of bleeding. As a precaution, concomitant use of clopidogrel and rifampicin should be discouraged.

Rifampicin treatment reduces the systemic exposure of oral contraceptives. Patients on oral contraceptives should be advised to use alternative, non-hormonal methods of birth control during Rifadin therapy. Also diabetes may become more difficult to control.

Concurrent use of ketoconazole and rifampicin has resulted in decreased serum concentrations of both drugs.

If *p*-aminosalicylic acid and rifampicin are both included in the treatment regimen, they should be given not less than eight hours apart to ensure satisfactory blood levels.

Effect of other medicinal products on Rifadin Oral Suspension

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

Other drug interactions with Rifadin Oral Suspension

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

Interference with laboratory and diagnostic tests
Therapeutic levels of rifampicin have been shown to inhibit standard microbiological assays for serum folate and Vitamin B12. Thus alternative assay methods should be considered. Transient elevation of BSP and serum bilirubin has been reported. Rifampicin may impair biliary excretion of contrast media used for visualization of the gallbladder, due to competition for biliary excretion. Therefore, these tests should be performed before the morning dose of rifampicin.

4.6. Pregnancy and lactation

Pregnancy

At very high doses in animals 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 antituberculosis drugs, on the human foetus is not known. Therefore, Rifadin should be used in pregnant women or in women of child bearing potential only if the potential benefit justifies the potential risk to the foetus. When Rifadin is administered during the last few weeks of pregnancy it may cause post-natal haemorrhages in the mother and infant for which treatment with Vitamin K1 may be indicated.

Lactation
Rifampicin is excreted in breast milk, patients receiving rifampicin should not breast feed unless in the physician's judgement the potential benefit to the patient outweighs the potential risk to the infant.

4.7. Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The following CIOMS frequency rating is used, when applicable:
Very common ≥ 10 %; Common ≥ 1 and <10%; Uncommon ≥ 0.1 and <1%;
Rare ≥ 0.01 and <0.1%; Very rare <0.01%, Unknown (cannot be estimated from available data).

Rifadin for Infusion is generally well tolerated and accepted by patients, although hypersensitivity reactions have been described and occasionally patients have experienced fever, skin rashes and nausea/vomiting.

Occasional instances of phlebitis and pain at the infusion site have been reported.

Reactions occurring with either daily or intermittent dosage regimens include:

System organ class	**Frequency**	**Preferred Term**
Infections and infestations	Unknown	Pseudomembranous colitis Influenza
Blood and lymphatic system disorders	Common	Thrombocytopenia with or without purpura, usually associated with intermittent therapy, but is reversible if drug is discontinued as soon as purpura occurs.
	Uncommon	Leukopenia
	Unknown	Disseminated intravascular coagulation Eosinophilia Agranulocytosis Hemolytic anemia Vitamin K dependent coagulation disorders
Immune system disorders	Unknown	Anaphylactic reaction
Endocrine disorders	Unknown	Adrenal insufficiency in patients with compromised adrenal function have been observed
Metabolism and nutritional disorders	Unknown	Decreased appetite
Psychiatric disorders	Unknown	Psychotic disorder
Nervous system disorders	Common	Headache Dizziness
	Unknown	Cerebral hemorrhage and fatalities have been reported when rifampicin administration has been continued or resumed after the appearance of purpura
Eye disorders	Unknown	Tear discolouration

Vascular disorders	Unknown	Shock Flushing Vasculitis Bleeding
Respiratory, thoracic and mediastinal disorders	Unknown	Dyspnoea Wheezing Sputum discoloured
Gastrointestinal disorders	Common	Nausea Vomiting
	Uncommon	Diarrhea
	Unknown	Gastrointestinal disorder Abdominal discomfort Tooth discolouration (which may be permanent)
Hepatobiliary disorders	Unknown	Hepatitis Hyperbilirubinaemia (see section 4.4)
Skin and subcutaneous tissue disorders	Unknown	Erythema multiforme Stevens-Johnson syndrome (SJS) Toxic epidermal necrolysis (TEN) Drug reaction with eosinophilia and systemic symptoms (DRESS) Acute generalized exanthematous pustulosis (AGEP) (see section 4.4) Skin reaction Pruritus Rash pruritic Urticaria Dermatitis allergic Pemphigoid Sweat discoloration
Musculoskeletal and connective tissue disorders	Unknown	Muscle weakness Myopathy Bone pain
Renal and urinary disorders	Unknown	Acute kidney injury usually due to renal tubular necrosis or tubulointerstitial nephritis Chromaturia
Pregnancy, puerperium and perinatal conditions	Unknown	Post-partum haemorrhage Fetal-maternal haemorrhage
Reproductive system and breast disorders	Unknown	Menstrual disorder
Congenital, familial and genetic disorders	Unknown	Porphyria
General disorders and administration site conditions	Very common	Pyrexia Chills
	Common	Paradoxical drug reaction (Recurrence or appearance of new symptoms of tuberculosis, physical and radiological signs in a patient who had previously shown improvement with appropriate anti-tuberculosis treatment is called a paradoxical reaction, which is diagnosed after excluding poor compliance of the patient to treatment, drug resistance,

		side effects of antitubercular therapy, secondary bacterial/fungal infections).*
	Unknown	Edema
Investigations	Common	Blood bilirubin increased Aspartate aminotransferase increased Alanine aminotransferase increased
	Unknown	Blood pressure decreased Blood creatinine increased Hepatic enzyme increased

* Incidence of paradoxical drug reaction: Lower frequency is reported as 9.2% (53/573) (data between October 2007 and March 2010) and higher frequency is reported as 25% (19/76) (data between 2000 and 2010).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Human Experience
• Signs and Symptoms:
Nausea, vomiting, abdominal pain, pruritus, headache and increasing lethargy will probably occur within a short time after acute ingestion; unconsciousness may occur when there is severe hepatic disease. Transient increases in liver enzymes and/or bilirubin may occur. Brownish-red or orange colouration of the skin, urine, sweat, saliva, tears and faeces will occur, and its intensity is proportional to the amount ingested. Facial or periorbital oedema has also been reported in paediatric patients. Hypotension, sinus tachycardia, ventricular arrhythmias, seizures and cardiac arrest were reported in some fatal cases.

The minimum acute lethal or toxic dose is not well established. However, nonfatal acute overdoses in adults have been reported with doses ranging from 9 to 12 g rifampicin. Fatal acute overdoses in adults have been reported with doses ranging from 14-60 g. Alcohol or a history of alcohol abuse was involved in some of the fatal and nonfatal reports.

Nonfatal overdoses in paediatric patients ages 1 to 4 years old of 100 mg/kg for one to two doses have been reported.

• Management:
Intensive supportive measures should be instituted and individual symptoms treated as they arise. Since nausea and vomiting are likely to be present, gastric lavage is probably preferable to induction of emesis. Following evacuation of the gastric contents, the instillation of activated charcoal slurry into the stomach may help absorb any remaining drug from the gastrointestinal tract. Antiemetic medication may be required to control severe nausea and

vomiting. Active diuresis (with measured intake and output) will help promote excretion of the drug. Haemodialysis may be of value in some patients.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Rifampicin is an active bactericidial antituberculosis drug which is particularly active against the rapidly growing extracellular organisms and also has bactericidial activity intracellularly. Rifampicin has activity against slow and intermittently-growing *M. Tuberculosis.*

Rifampicin inhibits DNA-dependent RNA polymerase activity in susceptible cells. Specifically, it interacts with bacterial RNA polymerase but does not inhibit the mammalian enzyme. Cross-resistance to rifampicin has only been shown with other rifamycins.

5.2 Pharmacokinetic properties

Rifampicin is readily absorbed from the gastrointestinal tract. Peak serum concentrations of the order of 10 µg/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 are 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.

Rifampicin is rapidly eliminated in the bile and an enterophepatic circulation ensues. During this process, rifampicin undergoes progressive deacetylation, so that nearly all the drug in the bile is in this form in about 6 hours. This metabolite retains essentially complete antibacterial activity. Intestinal reabsorption 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.

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

5.3. Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Agar
Sucrose
Methyl-p-hydroxybenzoate (E218)
Propyl-p-hydroxybenzoate (E216)
Potassium sorbate
Sodium metabisulphite (E223)
Tween 80
Raspberry essence (Contains small amount of ethanol)
Saccharin
Diethanolamine
Purified water

6.2. Incompatibilities

None stated

6.3. Shelf life

3 years from date of manufacture

6.4 Special precautions for storage

Do not store above 25°C.
Do not dilute.
Dispense in clear or amber glass bottles.

6.5. Nature and content of container

120ml in amber glass bottles

6.6. Instructions for use, handling and disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Aventis Pharma Limited
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Trading as:

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8. MARKETING AUTHORISATION NUMBER

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9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

04/03/1987 / 23/03/2005

10 DATE OF REVISION OF THE TEXT

20/07/2021