Sinerdol 150 mg, capsules  
Rifampicin  
Sinerdol 300 mg, capsules  
Rifampicin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet
1. What Sinerdol is and what it is used for
2. What you need to know before you take Sinerdol
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1. WHAT SINERDOL IS AND WHAT IT IS USED FOR

Sinerdol is part of a group of medicines known as antimycobacterials, used in the treatment of tuberculosis.
Sinerdol is recommended in the treatment of tuberculosis in association with other antituberculosis medicines, and also in the treatment of other infections caused by sensitive germs, such as: leprosy, brucellosis, legionellosis. Also recommended in meningococcus carriers (without displaying any symptom of disease) in order to limit the spread of the disease.
Sinerdol may be recommended by your doctor for other severe infections, but it will not be used in cold, flu, or other viral affections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SINERDOL

Do not take Sinerdol:
- If you are allergic to rifampicin or to any of the other ingredients of Sinerdol
- if you suffer from porphyria or other liver disease associated with jaundice
- if you follow a treatment with medicines named proteases inhibitors (amprenavir, indinavir, nelfinavir, ritonavir, lopinavir/ritonavir, saquinavir) or delavirdine.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Sinerdol.
Sinerdol should only be given under medical supervision.
Patients with impaired liver function should be given Sinerdol only in cases of necessity and under strict medical supervision. In these patients, rifampicin should be given in low doses and careful monitoring of liver function, especially SGPT/ALT and SGOT/AST should be carried out during 2 first weeks of therapy (especially in case of association with isoniazid) and then every 2 weeks during therapy. If signs of hepatocellular damage occur, rifampicin should be withdrawn.
Rifampicin treatment should be initiated with caution in patients with a pre-existing liver disease, alcoholism, in elderly patients or under the age of 2 years and malnourished patients, especially in case of association with isoniazid.

Rifampicin may affect the results of some blood tests: Coombs test, tests for folate, vitamin B12; urinalysis based on colorimetric reactions or spectrophotometry; serum uric acid, bilirubin, transaminases.

Rifampicin may determine reddish colour in your urine, saliva, tears and sweat, and patients should be forewarned of this. The red colour may stain soft contact lenses.

The intermittent administration of rifampicin has been reported to be associated with an immunological reaction.

If you use oral contraceptives, replace them with non-hormonal contraceptives, during treatment with rifampicin, to avoid unwanted pregnancy.

Other medicines and Sinerdol
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription.

If Sinerdol is used while taking other medicines, it may modify their efficacy.

Please tell your doctor if you are taking, or have recently taken, other medicines such as:
- proteases inhibitors (amprenavir, indinavir, nelfinavir, ritonavir, lopinavir/ritonavir, saquinavir);
- anticonvulsant medicines, antiarrhythmics, beta-adrenergic blockers, calcium channel blockers, - glucocorticoids, anti-diabetic sulphonamides, oral anticoagulants, digoxin, concurrent use of estrogen-progesterone contraceptives, antiepileptics (eg lamotrigine, sodium valproate, carbamazepine), barbiturates, chloramphenicol, clarithromycin, doxycycline, fluoroquinolones, antiretroviral drugs (e.g. zidovudine), cyclophosphamide, cyclosporine, methadone, theophylline;
- isoniazid, halothane.

Antacids or p-aminosalicylic acid should be taken at least 4 hours after Sinerdol in order to avoid the reducing of the absorption of rifampicin.

Reduced biliary excretion of contrast media used for visualization of the gallbladder have also been observed.

Rifampicin causes an abnormal bromosulphthalein excretion. Therefore, these tests should be performed before the morning dose of rifampicin.

Sinerdol with food and drink
Food may slow rifampicin absorption. This is why Sinerdol should be taken with 30 minutes before meals. If you cannot tolerate it, your doctor may allow you to take Sinerdol with food.
Avoid alcoholic beverages during Sinerdol treatment, because they may increase the risk of severe hepatic disorders.

Pregnancy and breast-feeding
Do not take Sinerdol during pregnancy or breast-feeding.

Driving and using machines
Sinerdol does not influence the ability to drive or use machines.

Sinerdol contains lactose monohydrate. If your doctor warned you about your intolerance to certain categories of glucides, please ask him before taking any medicine.

Sinerdol contains Amaranth (E123), which may cause allergic reactions.

Sinerdol contains methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216). Therefore, it may cause allergic reactions (even delayed) and exceptionally, bronchospasm.
3. HOW TO TAKE SINERDOL
Always take Sinerdol exactly as your doctor has told you. You must check with your doctor or pharmacist if you are unsure.
Take Sinerdol by mouth, swallow the capsules whole, with a drink of water.
Daily dose depend on patient’s bodyweight.
Sinerdol should be taken at least 30 minutes before a meal or 2 hours after a meal for an efficient and quick absorption.

Tuberculosis
To avoid selection of drug-resistant strains, Sinerdol must be taken concomitantly with other medicine for tuberculosis.

Adults
The recommended daily dose is 8-12 mg/kg of body weight.
The usual daily dose: Patients weighing less than 50kg: 450mg; Patients weighing more than 50kg: 600mg.

Children: 10mg to 20mg per kilogram of body weight daily. The maximum daily dose is 600mg.

Leprosy
The monthly dose is 600 mg of rifampicin. An alternative treatment can be used daily. The single daily dose is 10 mg/kg of body weight.
The usual daily dose: Patients weighing less than 50kg: 450 mg; Patients weighing more than 50kg: 600 mg.
Sinerdol should always be given with other medicine for leprosy.

Brucellosis, Legionnaires Disease or other serious bacterial infections

Adults: 600mg to 1200mg daily. The dose is given in 2 to 4 divided doses together with another antibiotic in order to prevent bacterial resistance.

Prophylaxis of Meningitis

Adults: 600mg twice per day for two days.

Children (1-12 years old): 10 mg/kg of body weight twice per day for two days

Children (3 months - 1 year old): 5mg per kilogram twice per day for two days

Prophylaxis of Haemophilus Influenzae:

Adults and children: 20 mg per kilogram body weight daily for 4 days in a single dose. No more than 600 mg per day should be given in children for 4 days.
Neonates: 10mg/kg/day for 4 days.

Impaired liver function: not more than 8mg of rifampicin per kilogram of body weight daily.
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, caution should be exercised in using Sinerdol in such patients, especially if there is evidence of impaired liver function.

If you take more Sinerdol than you should
Taking too much of any medicine may have serious consequences. If you suspect an overdose, tell your doctor immediately. The rifampicin overdose symptoms are: nausea, vomiting, abdominal pain, headaches, sleepiness, loss of consciousness. The “red man syndrome” may also occur: reddish or orange colouration of the skin, sweat, tears. In some severe cases the decreases of blood pressure and irregular heartbeat have been reported. In children, swelling of the faces and eyes may happen.

If you forget to take Sinerdol
If you forget a dose, take the medicine as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose and continue as usual. Do not take a double dose unless your doctor has told you otherwise.

If you stop taking Sinerdol
Follow the treatment as directed by your doctor. If you stop treatment too early, the infection may return. The intermittent treatment of rifampicin may cause the increase of adverse reactions frequency.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sinerdol can cause side effects, although not everybody gets them. The side effects are classified as follows:

Very common (affect more than 1 in 10 patients treated)
Common (affect less than 1 in 10 patients treated)
Uncommon (affect less than 1 in 100 patients treated)
Rare (affect less than 1 in 1000 patients treated)
Very rare (affect less than 1 in 10000 patients treated)
Not known (cannot be estimated from the available data)

Common
- flushing and itching with or without transient rashes.

Uncommon
- urticaria

Rare
- disseminated intravascular coagulation (DIC)
- staphylococcal scalded skin syndrome, pemphigoid reaction, erythema multiforme including Stevens-Johnson syndrome, Lyell syndrome and vasculitis.
- adrenal insufficiency
- psychoses

Very rare
- eosinophilia, leukopenia, agranulocytosis.

Not known
- thrombocytopenia with or without purpura (intermittent therapy). This effect is reversible if the drug is discontinued. Cerebral haemorrhage has been reported when rifampicin administration has been continued.
- Other reactions which have occurred with intermittent dosage regimens include "flu" syndrome (such as episodes of fever, myalgia, headache, dizziness); the "flu" syndrome appears between the third and the sixth months of treatment reported in 20% of the patients. It can also occur wheezing, decrease in blood pressure, shock, anaphylaxis, acute haemolytic anaemia and acute renal failure, usually due to acute tubular necrosis or to acute interstitial nephritis.
- anorexia, nausea, vomiting, abdominal discomfort and diarrhoea. Pseudomembranous colitis
has been reported with the use of rifampicin.
- Hepatitis and abnormal liver function tests have been reported.
- Menstrual disturbances in women receiving long-term therapy with regimens containing rifampicin.
- Rifampicin produces reddish colouration of the urine, saliva, sweat and tears.

5. HOW TO STORE SINERDOL

Keep out of the reach and sight of children.

Store below 25 °C, in the original package.

Do not use after the expiry date is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice visible signs of deterioration of package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF PACK AND OTHER INFORMATION

What Sinerdol contains
Sinerdol 150 mg capsules
- The active substance is rifampicin. Each capsule contains 150 mg of rifampicin.
- The other ingredients: the content of capsule: lactose monohydrate, magnesium stearate, the capsule cap: titanium dioxide (E 171), Allura Red (E129), Amaranth (E123), gelatin, silica, sodium lauryl sulfate, glacial acetic acid, glycerol, methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216), capsule body: titanium dioxide (E 171), brilliant blue (E133), gelatin, silica, glacial acetic acid, glycerol, methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216).

Sinerdol 300 mg capsules
- The active substance is rifampicin. Each capsule contains 300 mg of rifampicin.
- The other ingredients: the content of capsule: lactose monohydrate, magnesium stearate, the capsule cap/body: titanium dioxide (E 171), Allura Red (E129), Amaranth (E123), gelatin, silica, sodium lauryl sulphate, glacial acetic acid, glycerol, methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216), capsule body: titanium dioxide (E 171), gelatin, silica, glacial acetic acid, glycerol, methyl parahydroxybenzoate (E 218) and propyl parahydroxybenzoate (E 216).

What Sinerdol looks like and contents of the pack
Sinerdol 150 mg is presented as size “2” capsules, with opaque red cap/opaque blue body, containing a reddish-brown powder.

Sinerdol 300 mg is presented as size “1” capsules, with opaque red cap/opaque red body, cylindrical shape, containing a reddish-brown powder.

Sinerdol 150 mg capsules

Outer carton with 2 PVC/Al blisters of 10 capsules.
Cardboard box with 100 PVC/Al blisters of 10 capsules.
Not all pack sizes may be marketed.
Sinerdol 300 mg capsules

Outer carton with 1 PVC/Al blister of 10 capsules. Cardboard box with 100 PVC/Al blisters of 10 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
ANTIBIOTICE SA
1 Valea Lupului Street, 707410, Iasi, Romania, EU

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Romania
ANTIBIOTICE S.A.
1 Valea Lupului Steet, 707410, Iasi, Romania, EU

This leaflet was last revised in May, 2012.