ROYCE RIFAMPICIN CAPSULE

Rifampicin (150, 300 mg)

What is in this leaflet

- 1. What Royce Rifampicin Capsule is used for
- 2. How Royce Rifampicin Capsule works
- 3. Before you use Royce Rifampicin Capsule
- 4. How to take Royce Rifampicin Capsule
- 5. While you are using Royce Rifampicin Capsule
- 6. Side effects
- 7. Storage and disposal of Royce Rifampicin Capsule
- 8. Product description
- 9. Manufacturer and Product registration holder
- 10. Date of revision

What Royce Rifampicin Capsule is used for

Royce Rifampicin Capsule is used for the treatment of tuberculosis in combination with other antibiotics.

How Royce Rifampicin Capsule works

The active ingredient, rifampicin, is an antibiotic that belongs to a group of medicine called rifampin. It works by killing or stopping the growth of bacteria and other organisms causing nontuberculosis and tuberculosis infections.

Before you use Royce Rifampicin Capsule

When you must not use it:

Do not take Royce Rifampicin Capsule if you are:

- have jaundice (liver disease).
- allergic to rifampicin or any other ingredients used in this medicine.
- in first trimester of pregnancy, premature and newborn infants.
- Concomitant saquinavir / ritonavir therapy

-Before you start to use it:

Tell your doctor of pharmacist if:

- you have allergies to any other medicines, foods, preservatives or dyes.
- you have liver failure.
- you have any signs of an overt meningococcal infection.

- Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of the other medications or take other precautions.

How to take Royce Rifampicin Capsule

- How much to use:

Follow all directions given to you by your doctor and pharmacist carefully. The dose will vary from individual to individual. Your doctor will decide the right dose for you.

-When to use it:

Your doctor will decide when it is appropriate for you to use Royce Rifampicin Capsule according to the type of condition you have.

-How long to use it:

Continue taking the tablets for as long as your doctor recommends, unless you have any problems. In that case, check with your doctor.

-If you forget to use it:

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, wait until the usual time to take your medicine. Do not double your dose to make up for forgotten doses.

-If you use too much (overdose):

If you accidently take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You might need urgent medical attention.

While you are using Royce Rifampicin Capsule

<u>Things you must do</u>

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Royce Rifampicin Capsule.
- Tell your doctor immediately if you become pregnant while taking this medication.

-<u>Things you must not do</u>

• Do not stop taking the medicine unless advised by your doctor.

- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Royce Rifampicin Capsule to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

- Special care is recommended during pregnancy. The benefits must be assessed against possible effects on the child.
- May cause liver impairment. Should be given with care to patients with impaired liver function. Check with your doctor if you have fever, vomiting, jaundice or other deterioration your conditions.
- Hypersensitvity to drug. Check with your doctor if you experienced fever, swelling of lymph nodes or rash or swelling during the course of the treatment

Side effects

Like all medicines, Royce Rifampicin Capsule can cause side effects, although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- *Cutaneous reactions* flushing and itching with or without a rash.
- *Gastrointestinal reactions* eating disorder, nausea, vomiting, abdominal discomfort and diarrhoae.
- *Hepatitis* can be caused by rifampicin and liver function tests should be monitored.
- *Thrombocytopenia* with or without purpura (blood spots).
- Others pseudomembranous colitis (severe colonic disease), cerebral bleed, fatalities, eosinophilia (abnormal increase in the number of white blood cells). leukopenia (reduction in the number of white cells in the blood), edema (swelling caused by excess fluid in body tissues), muscle weakness, myopathy (muscle chills, headache, disease), fever. pain, bone occasional dizziness, disturbances of the menstrual cycle, reddish discolouration of the urine, sputum (mixture of saliva and mucus coughed up from the respiratory tract) and tears.

ROYCE RIFAMPICIN CAPSULE

Rifampicin (150, 300 mg)

Storage Rifampic	-	of	Royce	SG : SINXXXXXP
-Storage:				Manufacturer

Keep container tightly closed. Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

-Disposal:

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose the medicines you no longer required. These measures will help to protect the environment.

Product description

-What it looks like:

Royce Rifampicin Capsule 150mg:

Size 2 capsule with opaque blue coloured cap and opaque green coloured body.

-Ingredients: Active Ingredient: Rifampicin 150mg.

Inactive Ingredient:

Corn starch, Magnesium stearate, Deionized water, Sodium lauryl sulphate, Povidone, Propyl paraben, methyl paraben, Erythrosine (E127), Sunset Yellow FCF (E110), Brilliant Blue (E133), Titanium Dioxide (E171), Quinoline Yellow (E104) and Gelatin.

Royce Rifampicin Capsule 300mg:

Size 0 capsule with opaque brown coloured cap and opaque pink coloured body.

-Ingredients: Active Ingredient Rifampicin 300mg.

Inactive Ingredients:

Corn starch, Magnesium stearate. Deionized water, Sodium lauryl sulphate, Povidone, Propyl paraben, methyl paraben, Brilliant Blue FCF (E133), Quinone Yellow (E104), Carmoisine (E122), Titanium Dioxide (E171) and Gelatin.

-Product Registration No.: Royce Rifampicin Capsule 150mg: MY: MAL19860793AZ SG : SINXXXXP

Royce Rifampicin Capsule 300mg: MY: MAL19860827AZ

and Product **Registration Holder**

Royce Pharma Manufacturing Sdn. Bhd.

PT 1663, Nilai Industrial Estate, 71800 Nilai, Negeri Sembilan, Malaysia.

Date of revision 01/09/2022