Distribution:
- After oral administration of spiramycin 6 M.I.U.,
  The peak serum concentration is 3.3 ug/ml.
  - The half-life is about 8 hours.
  - Excellent diffusion occurs in the saliva, and excellent diffusion in the tissues (lungs:
    from 20 to 60 ug/g; tonsils: from 20 to 80 ug/g; infected sinuses: from 75 to 110
    u/g; bone: from 5 to 100 u/g), ten days after discontinuation of treatment 5, to 7
    u/g of active constituent persists in the spleen, liver and kidneys.

Excretion:
- Biliary elimination is very extensive; levels are 15 to 40 times higher than those in
  serum.
- High quantities are found in the feces.
- Only 10% of the ingested dose is found in urine.

Metabolism:
- Spiramycin is slowly inactivated in the liver, with formation of unknown metabolites.

Indications:
These are derived from the antibacterial activity and the pharmacokinetic characteristics of spiramycin. They take into account both clinical studies involving the drug and its position in the currently available range of antibacterial products.

They are limited to:
- Infections caused by micro-organisms defined as being sensitive (see Pharmacodynamics section), notably the following: ENT, bronchopulmonar, stomatological, cutaneous, genital (in particular prostatic), and bone infections. - Prophylaxis of meningococcal meningitis where there is a contraindication to Rifampicin: the aim is eradication of Neisseria meningitides from the nasopharynx.
- Spiramycin is not a treatment for meningococcal meningitis, it is recommended for prophylaxis in:
  - Patients after curative treatment and before return to the community.
  - Subjects exposed to the oropharyngeal secretions of patients during the 10 days prior to hospitalization.
  - Chemoprophylaxis in acute rheumatic fever in subjects allergic to penicillin.
  - Toxoplasmosis in pregnant females.

Dosage and Administration:
- 2 to 3 tablets 3 M.I.U. or 4 to 6 tablets 1.5 M.I.U. (i.e. 6 to 9 M.I.U.) daily, in 2 or 3 separate doses.
- Prophylaxis of meningococcal meningitis: 3 M.I.U. / 12 hours.

Side effects:
- Nausea, vomiting, diarrhea and very rare cases of pseudo-membranous colitis have been reported.
- Hypersensitivity reactions: Rash, pruritus, pruritus.
- Very rare angioedema, anaphylactic shocks.
- Isolated cases of vasculitis, including Henoch-Schonlein purpura.
- Rash, urticaria, pruritus.
- Anaphylactic reactions:
- Gastrointestinal effects:
  - Occasional cases of transient paresthesia.
  - Very rare cases of acute hemolysis have been reported.
  - Liver: Very rare cases of liver tests function abnormalities have been reported.
  - Hematology:
  - Very rare cases of acute hemolysis have been reported.

Drugs interactions:
- Levodopa: Inhibition of absorption of carbidopa with decreased levodopa plasma
  levels. Where necessary, patients should be closely monitored and the levodopa
  dosage levels adjusted.
- Contra-indications:

Precaution & warning:
- As very rare cases of acute hemolysis have been reported in patients with glucose 6-phosphate dehydrogenase deficiency, the use of spiramycin in this patient population is not recommended.

Packaging:
- Carton box contains 1 (Al/PVC) strip contains 10 tablets + insert leaflet.
- Storage:
  - Store at temperature not exceeding 30ºC in a dry place.

Produced by:
DELTA PHARMA S.A.E
Tenth of Ramadan City , A.R.E
يلقuerdo que el tratamiento antibiótico en niños debe ser indicado por un profesional médico. No se debe administrar antibióticos sin una correcta prescripción médica.

El uso de antibióticos debe ser riguroso para prevenir la resistencia a los mismos.

Es importante tener en cuenta que la duración del tratamiento antibiótico debe ser lo más breve posible, de acuerdo con la guía clínica recomendada por el profesional médico.

En caso de tratamiento antibiótico, es fundamental seguir las indicaciones del médico para evitar el desarrollo de resistencia a los antibióticos y para garantizar un tratamiento eficaz.

La conservación adecuada de los medicamentos es fundamental para el correcto uso de los antibióticos.

En caso de tratamiento con antibióticos, es importante seguir las indicaciones del médico para evitar el desarrollo de resistencia a los mismos.