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Spirex Plus

Film Coated Tablet

Company name: Medical Union Pharmaceuticals
Trade name: Spirex Plus Film Coated Tablet
Generic name: Spiramycin plus Metronidazole.
Composition: Each film coated tablet contains:
Active ingredient: Spiramycin 379 mg equivalent to Spiramycin 1.5 M.I.U. Metronidazole 250 mg.
- **Inactive ingredient:** Croscarmellose sodium, Colloidal silicon dioxide, polysorbate 80, Magnesium Stearate, Microcrystalline Cellulose, Hydroxy propyl methyl cellulose, Polyethylene glycol 6000, Titanium dioxide, Talc, antifoam emulsion.

Pharmaceutical form: Film coated tablets

Pharmacological action:
Spiramycin is a macrolide antimicrobial agent. It binds to the 50 S subunit of bacterial ribosomes, resulting in blockage of the transpeptidation reactions, inhibiting protein synthesis and subsequent cell growth. It is primarily bacteriostatic, but may be bactericidal against more sensitive strains when used in high concentrations.
Metronidazole is an antimicrobial drug that is bactericidal to anaerobic and microaerophilic microorganisms, both bacteria and protozoa through reduction the nitro group of metronidazole intracellularly, the reduction product disrupts DNA and inhibits its synthesis in microorganism cell.

Pharmacokinetics:
Spiramycin absorption is incomplete, with an oral bioavailability of 33% to 39% The administration with food reduces bioavailability by 50% so it should be given on an empty stomach. Spiramycin is highly concentrated in tissues and body fluids. Its half-life is 5.5 to 8 hours after oral administration and time to peak concentration 3-4 hours . It metabolized in the liver to active metabolites.
Over 80% of administrated dose is excreted in bile and 4-14 % excreted in urine.
Metronidazole absorption: About 80% of an oral dose is absorbed, with peak serum concentrations occurring at about one hour. Food delays peak concentrations to about two hours.
Metronidazole is distributed into most body tissues and fluids including (CSF) cerebrospinal fluid, bone, bile, saliva, pleural and peritoneal fluids, vaginal secretions, seminal fluids, middle ear fluid, and hepatic as well as cerebral abscesses. CSF levels approach serum levels in patients with inflamed meninges; they reach about 50% of serum levels in patients with uninflamed meninges. Less than 20% of metronidazole is bound to plasma proteins. It readily crosses the placenta.
Metronidazole metabolism: It is metabolized, primarily in the liver.
Excretion: About 20% of a metronidazole dose is excreted unchanged in urine; about 6% to 15 % is excreted in feces. Metronidazole's half-life is 6-8 hours in adults with normal renal function; the half-life may be prolonged in patients with impaired hepatic function.
Metronidazole is secreted into breast milk.

Indications:
Spirex Plus is highly effective in treatment of:
- Acute and chronic periodontal infections as periodentitis, Gingivitis and Stomatitis.
- Upper respiratory tract infection: Pharyngitis, Tonsillitis, Sinusitis and Otitis media.
- Prevention of local post- operative infection complication in odontogenic infection.

Dosage and administration:
The oral dose should be taken before meals twice daily.

Contraindications:
Hypersensitivity to Spiramycin or Metronidazole.

Side effects:
Dermatologic: rash, urticaria, pruritus.
Gastrointestinal: nausea, vomiting, diarrhea.
Hepatic: transaminases increased.

Drug interactions:
Disulfiram-like reaction occurs with concomitant administration of alcohol. The effect of oral anticoagulants is enhanced with use of Metronidazole.

Pregnancy and lactation:
The drug should be given only if the potential benefit outweighs the potential risk to the fetus or baby.

Precautions and warning:
- Patients with a history of blood dyscrasia, because the drug can cause leukopenia.
- Patients with severe hepatic or severe renal impairment, (use at lower than recommended dose) because metronidazole and its metabolites accumulate in the plasma.
- Patients with peripheral neuropathy and seizure disorders, as they can be exacerbated in some patients.
- Avoid alcohol and alcohol-containing medications during therapy and for at least 48 hours after the last dose to prevent disulfiram-like reaction.
- If therapy exceeds 10 days, regular clinical and laboratory monitoring is advised.

Package and storage:
Carton box containing 2 (AL/PVC) strips each of 10 film coated tablets + insert leaflet.
Store at a temperature not exceeding 30°C in a dry Place.

Instructions to patients:
Keep away of reach of children.

Produced by:
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