

SPIRAGYL® Forte Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about SPIRAGYL Forte

Each tablet of SPIRAGYL Forte for oral administration contains:

Spiramycin 1500000 IU

Metronidazole 250 mg

Excipients are: lactose, microcrystalline cellulose, and magnesium stearate.

SPIRAGYL Forte is an association of spiramycin, a macrolide antibiotic and metronidazole, an imidazole derivative. SPIRAGYL Forte is reserved for the treatment of dentibuccal infections. Spiramycin and metronidazole have synergistic effects and act against a large number of bacteria.

SPIRAGYL Forte is indicated for the treatment of acute, chronic or recurrent stomatological infections: dental abscesses, phlegmons, peri-maxillary cellulitis, pericoronitis, gingivitis, stomatitis, periodontitis, parotiditis, and submaxillaritis.

SPIRAGYL Forte is also indicated for the prevention of local, postoperative infectious complications following dental and oral surgeries.

The way to take SPIRAGYL Forte

Take SPIRAGYL Forte as directed by your physician or your dentist.

SPIRAGYL Forte is reserved for the treatment of adults and children over 15 years of age.

The usual recommended doses are:

Indication	Dosage
Treatment of acute, chronic or recurrent stomatological infections	2 to 3 tablets per day in 2 or 3 divided doses, to be taken during meals. In severe cases, the dosage can be increased up to 4 tablets per day.
Prevention of local, postoperative infectious complications following dental and oral surgeries	2 to 3 tablets per day in 2 or 3 divided doses, to be taken during meals.

Duration of treatment

The duration of treatment will be decided by your doctor. Do not discontinue your treatment without consulting your doctor, even if you begin to feel better; your symptoms may start to improve before the infection is completely treated.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- History of hypersensitivity to any of the components or to imidazole derivatives
- Children less than 15 years of age

Precautions

- Discontinue the treatment in case of dizziness, ataxia or mental confusion.
- Avoid alcoholic beverages or drugs containing alcohol while taking this drug.
- This drug should be administered with caution in case of nervous system diseases. During prolonged treatment, patients must be monitored for the appearance of signs suggestive of central or peripheral neurological reactions.
- Inform your doctor immediately in case of occurrence of a generalized erythema with pustules and accompanied by fever. Treatment must be discontinued and any further administration of spiramycin, either alone or in combination, is contraindicated.
- The use of spiramycin is not recommended in patients with glucose-6-phosphate-dehydrogenase deficiency.
- Blood tests are recommended, specifically leukocyte count, in case of history of hematological disorders, treatment with high doses or during long-term treatment.
- Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug may be used in pregnancy if needed. Avoid the use of this drug during lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently. Concomitant administration with disulfiram is not recommended. Avoid the use of alcohol or drugs containing alcohol while taking this drug. Caution should be taken when used with fluorouracil, levodopa, and oral anticoagulants.

Adverse reactions

Reported adverse reactions include: stomach pain, nausea, vomiting, diarrhea, glossitis, dry mouth, stomatitis, metallic taste, loss of appetite, rash, urticaria, pruritus, flushing, occasional and transient paraesthesia, headache, seizure, dizziness, ataxia, confusion, hallucinations, peripheral sensory neuropathy, and a brown reddish coloration of urine.

Rarely reported adverse reactions include: generalized erythema with pustules and accompanied by fever, pseudomembranous colitis, hypersensitivity reactions, liver function disorders, cholestatic hepatitis, reversible pancreatitis, and blood disorders.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

SPIRAGYL *Forte*, spiramycin 1500000 IU and metronidazole 250 mg, pack of 10 tablets

Issue date: 09/2013

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