

MEDSPIRAGYL® 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 MEDSPIRAGYL

Each tablet of MEDSPIRAGYL for oral administration contains:

Spiramycin 750000 IU

Metronidazole 125 mg

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

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

MEDSPIRAGYL 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.

MEDSPIRAGYL is also indicated in surgical infection prophylaxis for the prevention of post-operative local infections after dental or buccal surgeries.

The way to take MEDSPIRAGYL

Take MEDSPIRAGYL as directed by your physician or your dentist. The usual recommended doses are:

Age	Dose
Adults	2 tablets every 12 hours or 2 tablets every 8 hours, during meals; in the curative treatment of severe cases the dosage can be increased up to 8 tablets per day.
Children from 10 to 15 years	1 tablet every 8 hours during meals
Children from 6 to 10 years	1 tablet every 12 hours during meals

Duration of treatment

The duration of treatment is determined according to the disease process. Do not discontinue the treatment without consulting your doctor.

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 patients with a history of hypersensitivity to any of the components or to imidazole derivatives.

Precautions

-Discontinue the treatment if a hypersensitivity reaction occurs. 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, or metronidazole either alone or in combination, is contraindicated.

-Discontinue the treatment in case of dizziness, ataxia or mental confusion.

-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.

-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 busulfan, and disulfiram is not recommended. Avoid the use of alcohol or drugs containing alcohol while taking this drug.

Caution should be taken when used with anticonvulsants enzyme inducers, lithium, rifampicin, fluorouracil, oral anticoagulants, levodopa and carbidopa.

Adverse reactions

Reported adverse reactions include: stomach pains, nausea, vomiting, diarrhea, glossitis, dry mouth, stomatitis, metallic taste, loss of appetite, pancreatitis reversible upon discontinuation of treatment, rash, urticaria, pruritus, congestive flushes, Lyell's syndrome, Stevens-Johnson syndrome, headache, peripheral sensory neuropathy, convulsions, dizziness, confusion, and other disorders related to the nervous system, psychiatric disorders, visual disturbances, hepatic disorders, and a brown reddish coloration of urine.

Rarely reported adverse reactions include: pseudomembranous colitis, acute generalized exanthematous pustulosis, hypersensitivity reactions, and blood disorders.

Inform your doctor if any adverse reaction 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

MEDSPIRAGYL, spiramycin 750000 IU and metronidazole 125 mg, pack of 20 tablets

Issue date: 11/2015

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