

SPIRAGYL® 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

Each tablet of SPIRAGYL for oral administration contains:

Spiramycin 750000 IU

Metronidazole 125 mg

SPIRAGYL 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.

SPIRAGYL is indicated for the treatment of acute, chronic or recurrent stomatological infections:

dental abscesses, phlegmons, peri-maxillary cellulitis, pericoronitis, osteitis, periodontitis, submaxillaritis, parotiditis, gingivitis and stomatitis.

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

The way to take SPIRAGYL

Take SPIRAGYL as directed by your physician or your dentist. The usual recommended dosage is:

Age	Dosage
Adults	2 tablets every 12 hours or 2 tablets every 8 hours, during meals; in 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 5 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 treatment in case of dizziness, ataxia or mental confusion.
- This drug should be administered with caution in case of severe nervous system diseases.
- Avoid alcoholic beverages or drugs containing alcohol while taking this drug and for three days afterward.
- Leukocyte count is recommended in case of history of blood dyscrasia, treatment with high doses or during long-term treatment.
- This drug should not be administered during the first trimester of pregnancy and during lactation.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently. Concomitant administration of this medication with disulfiram and alcohol should be avoided. Caution should be taken when used with fluorouracil, levodopa and oral anti-coagulant drugs.

Adverse reactions

This drug is usually well tolerated when used as directed. Occasionally reported adverse effects were diarrhea, nausea, vomiting, gastric pain, hypersensitivity reactions, headache, taste perversion (metallic taste), dry mouth, loss of appetite, or a brown reddish coloration of urine.

Inform your doctor if any adverse 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, spiramycin 750000 IU and metronidazole 125 mg, pack of 20 tablets

Revision date: 03/2007

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