

PACKAGE LEAFLET: Information for the patient

SPIRAMICINE

Tablets – 750 000 UI

(Spiramycin)

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Spiramicine is and what it is used for
2. Before you take Spiramicine
3. How to take Spiramicine
4. Possible side effects
5. How to store Spiramicine
6. Other information

1. WHAT SPIRAMICINE IS AND WHAT IT IS USED FOR

Spiramicine is a macrolide antibiotic that has similar uses with erythromycin. Macrolides are weak bases; their activity increases at alkaline pH. Macrolides penetrate into the pleural fluid, in the ascitic fluid, in the middle ear exudates and in the sputum. When the meninges are inflamed, they can enter in the cerebrospinal fluid. Macrolides are used in respiratory tract, urogenital, digestive and skin soft tissue infections, especially when beta-lactamic antibiotics or tetracyclines are contraindicated.

Spiramicine is indicated in:

- the treatment of otorhinolaryngological, bronchopulmonary, stomatological, genital (especially of prostate origin), bone and skin infections;
- the prophylaxis of meningitis by meningococcus;
- the cases when rifampicin is contraindicated;
- the toxoplasmosis of old women.

Your doctor may have given Spiramicine to you for another purpose. Ask your doctor if you want to know why you have been given Spiramicine.

2. BEFORE YOU TAKE SPIRAMICINE

Do not take Spiramicine if:

- you are allergic to spiramycin or to any of the excipients of Spiramicine.

Take special care with Spiramicine

Ask your doctor before taking Spiramicine.

Since spiramycin passes into breast milk, it is advised by mothers to discontinue breast feeding while they are being treated with spiramycin.

Taking other medicines

Contact with your doctor or pharmacist if you are taking or have recently taken other drugs, including those obtained without a prescription. It is especially important that your doctor knows that you are being treated with:

- acenocumarol, warfarin, digoxin, because spiramycin and macrolides in general may increase their effect;
- ciclosporin, because it may be possible that spiramycin and the other macrolides may inhibit its metabolism (increase of the plasmatic concentration of ciclosporin);
- levodopa (given simultaneously with carbidopa), because spiramycin reduces its plasmatic levels, thus reducing its therapeutic effect.

Taking Spiramicine with food and drinks

Absorption of Spiramicine is reduced if taken with food.

Pregnancy and Breast - feeding

Ask for the advice of the pharmacist or of the doctor before taking this drug.

Since spiramycin passes into breast milk, mothers are advised to discontinue breast - feeding while they are being treated with spiramycin.

Driving and using machinery

It is not known if Spiramicine may affect the ability to drive and use machinery.

Important information about some of the excipients of Spiramicine

This drug contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE SPIRAMICINE

Always take Spiramicine tablets as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults: 3 000 000 - 4 500 000 UI daily, in 2 - 3 divided doses.

Children over 20 kg: 750 000 UI / 10 kg of body weight daily, in 2 - 3 divided doses.

Babies and little children: 375 000 - 750 000 UI / kg of body weight, in 2 - 3 divided doses.

For the prophylaxis of meningitis by meningococcus:

Adults: 1 500 000 UI, every 12 hours;

Children: 375 000 UI / kg of body weight, every 12 hours, for 5 days.

If you take more Spiramicine than you should

If you take more Spiramicine than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Spiramicine

If you forget a dose (or more doses), take the next dose when it is time to take it usually.

Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, Spiramicine may cause side effects, although not everybody manifests them. The possible side effects of Spiramicine are gastrointestinal disorders, such as: nausea, vomiting, diarrhea (these disorders may be the cause of treatment discontinuance), as also skin allergic reactions.

5. HOW TO STORE SPIRAMICINE

Keep away from children!

Do not use Spiramicine after the expiry date which is stated on the packaging.

Store below 25°C.

Store in the original packaging.

6. OTHER INFORMATION

What Spiramicine contains

The active substance is spiramycin.

Each tablet contains 750 000 UI spiramycin.

The excipients: starch, lactose, microcrystalline cellulose, magnesium stearate, talc and sodium starch glycolate.

Content of the pack:

Carton box with 30 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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