



PATIENT INFORMATION LEAFLET

BIOFLEKS METROSEL 0.5% IV Solution for Perfusion

It is administered by intravenous injection.

- **Active ingredient:** Each 100 ml of solution contains 500 mg of Metronidazole.
- **Excipients:** Disodium phosphate, Sodium chloride, Citric acid monohydrate, Water for Injection

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read again.
- If you have any further questions, ask your doctor or pharmacist.
- This medication is prescribed solely for you, do not offer it to others.
- If you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.
- Follow the instructions in this leaflet exactly. Do not use **lower or higher** doses, except the dose you have been recommended.

In this Patient Information Leaflet:

1. ***What BIOFLEKS METROSEL 0.5% is and what is it used for?***
2. ***What you need to know before you use BIOFLEKS METROSEL 0.5%?***
3. ***How to use BIOFLEKS METROSEL 0.5%***
4. ***What are the possible side effects?***
5. ***How to store BIOFLEKS METROSEL 0.5%***

Headings are included.

1. What BIOFLEKS METROSEL 0.5% is and what is it used for?

BIOFLEKS METROSEL 0.5% solution for injection is used for intestinal amoebiasis (an infection caused by amoeba), hepatic amoebiasis, non-specific vaginitis (vaginal infection), anaerobic infections and genital infections caused by trichomonas.

BIOFLEKS METROSEL 0.5% is presented in 100 ml PVC Bag with two outputs, with protective HDPE Overpouch.

2. What you need to know before you use BIOFLEKS METROSEL 0.5%?

Do not use BIOFLEKS METROSEL 0.5%

It should not be used in patients with hypersensitivity to imidazole derivatives or the excipients in the drug.



Use BIOFLEKS METROSEL 0.5% CAREFULLY

- If you have experienced or currently have liver problems.
- If you are on dialysis because of kidney failure.
- If you have a disease related to your nervous system.
- You should avoid alcohol during treatment and you should not drink alcohol at least for 48 hours after the treatment.
- Metronidazole should be used with caution in cases with a medical history of genetic blood disease.
- In cases where long-term BIOFLEKS METROSEL 0.5% use is required, long-term use should be carefully evaluated.

Use of BIOFLEKS METROSEL 0.5% with food and drinks

BIOFLEKS METROSEL 0.5% solution for injection can be used on an empty or full stomach as it is administered intravenously.

Pregnancy

Consult your physician or your pharmacist before using the drug.

BIOFLEKS METROSEL 0.5% should not be used during the first 3 months of pregnancy. After the first 3 months of pregnancy, it should be used only if deemed absolutely necessary by the physician.

If you notice you are pregnant during treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or your pharmacist before using the drug.

As BIOFLEKS METROSEL 0.5% is excreted into breast milk, it should not be used in breast-feeding mothers.

Driving and using machines

During treatment with BIOFLEKS METROSEL 0.5%, side effects may occur which may affect your ability to drive and use machines (e.g; confusion, dizziness, hallucinations, visual disturbances etc.) If you drive experience such side effects, do not drive or use machines.

Important information about some excipients present in BIOFLEKS METROSEL 0.5%

Patients on low sodium and low salt diet should be careful as it contains sodium.

Use with other medicines

When used in combination with disulfiram treatment, metronidazole may cause confusion and other psychological reactions.

Patients receiving warfarin therapy should be careful.

Also inform your doctor if you are being treated with the following drugs:

Lithium, vecuronium, phenobarbital or phenytoin, 5-fluorouracil, busulfan, cyclosporine

If you are using or have recently used any type of prescription or non-prescription drugs, please inform your physician or your pharmacist.



3. How to use BIOFLEKS METROSEL 0.5%

Instructions for appropriate use and dose / administration frequency:

BIOFLEKS METROSEL 0.5% solution for injection is a drug used in specific circumstances. Your doctor will determine the appropriate dose and frequency of administration depending on your condition and the severity of your disease.

Route and method of administration

It is administered by intravenous injection.

Various age groups:

Use in children:

BIOFLEKS METROSEL 0.5% is used in children.

Use in elderly:

BIOFLEKS METROSEL 0.5% should be used with caution in the elderly, particularly if used in high doses.

Special conditions of use:

Renal/Hepatic impairment:

It should be used with caution in patients on dialysis with kidney failure as it is excreted via urine. Your doctor may apply lower doses or shorter treatment in patients with liver failure.

Your doctor will decide and apply your dose according to your disease.

If you have the impression that the efficacy of BIOFLEKS METROSEL 0.5% is too strong or too weak, talk to your doctor or pharmacist.

If you have used more BIOFLEKS METROSEL 0.5% than you should

If you have used more BIOFLEKS METROSEL 0.5% than you should, talk a doctor or pharmacist.

If you forget to use BIOFLEKS METROSEL 0.5%

Do not take a double dose to make up for forgotten doses.

If you forget a BIOFLEKS METROSEL 0.5% dose, you should take your next dose as normal.

If you have any additional questions regarding the use of this product or ask your doctor or pharmacist.

Effects which may occur when treatment with BIOFLEKS METROSEL 0.5% is discontinued

Metronidazole withdrawal is not expected to have any impact potential.

4. What are the possible side effects?

As with all medicines, there may be side effects in people who are sensitive to the ingredients of BIOFLEKS METROSEL 0.5%.

If you notice any of the following, stop using BIOFLEKS METROSEL 0.5% and inform your doctor IMMEDIATELY, or apply to the emergency service of the nearest hospital:

- Swelling in your hands, feet, joints, face, lips or throat that can lead to difficulty in breathing or swallowing. Also you may notice an itchy rash. This indicates that you have developed an allergic reaction against BIOFLEKS METROSEL 0.5%.
- A severe but rare effect is a brain disease called encephalopathy. Symptoms vary, but you may have a fever, neck stiffness, headaches or you might hear sounds that do not exist. You also may have difficulty using your hands and your feet, it can be difficult to talk or you may feel dizziness.

All of these are very serious side effects.

If you experience any of them, you may need urgent medical attention or to be admitted to a hospital.

If you notice any of the following, inform your doctor immediately, or apply to the emergency service of the nearest hospital:

- Yellowish appearance of the skin and eyes. This may indicate liver disease (jaundice). In patients treated with metronidazole in combination with other antibiotics, hepatic failure requiring liver transplantation has been reported.
- Unusual infections, mouth sores, bruising, bleeding gums, or fatigue. This may occur because of a blood problem.
- Severe abdominal pain reflected in your back (pancreatitis)

All of these are very serious side effects. Urgent medical intervention may be required. These serious side effects are very rare.

If you notice any of the following, please tell your doctor:

Very rare (<1/10 000)

- Seizures
- Mental problems such as dizziness and hearing or seeing things that are not there (hallucinations)
- Skin rashes or redness
- Eye problems such as blurred or double vision
- Headache
- Darkening of urine color
- Somnolence or dizziness

- Muscle or joint pain

Frequency not known (it cannot be estimated from available data)

- Insensitivity, tingling, pain or fatigue in arms and legs
- Unpleasant taste in mouth
- Coated tongue
- Nausea, vomiting, stomach discomfort or diarrhea
- Loss of appetite
- Fever
- Mental depression sensation
- Pain in eyes (optic neuritis)
- A group of symptoms occurring together such as, fever, headache, neck stiffness, extreme sensitivity to light, nausea and vomiting. This situation may be caused as a result of inflammation of the membrane surrounding the brain and spinal cord (meningitis).

If you experience any side effect not mentioned in this patient information leaflet, inform your doctor or your pharmacist.

5. How to store BIOFLEKS METROSEL 0.5%

Keep BIOFLEKS METROSEL 0.5% out of the sight and reach of children, and in its packaging.

Solution for injection should be stored at ambient temperature between 15° - 30°C and protected from direct daylight.

Use in compliance with the expiry date.

Do not use BIOFLEKS METROSEL 0.5% after the expiration date stated on the packaging.

Expiry date corresponds to the last day of that month.

Drugs should not be disposed with waste water or your household rubbish. Ask your pharmacist how to dispose of unused drugs. These measures will contribute to protecting the environment.

Marketing authorization holder and manufacturing site:

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