

# Flagyl®

# 500mg

metronidazole

## Pessaries

### Read all of this leaflet carefully before using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions or are unsure of anything, please ask your doctor or your pharmacist for more information.
- This medicine has been prescribed for you personally and you must not pass it on to others. It may harm them, even if their symptoms are the same as yours.

## IDENTIFICATION OF THE MEDICINE

**Composition**  
metronidazole.....500mg  
Excipients: hard fat.

## Pharmaceutical form and presentation

Pessary. (Box of 10).

## Pharmaco-therapeutic class

Antibiotic, antibacterial and antiparasitic agent belonging to the 5-nitroimidazole group (6-aminoflavins and antiseptics, excl. combinations with corticosteroids - imidazole derivatives) ATC code : G01AF01

## Holder

sanofi-aventis France  
1-13, boulevard Romain Rolland  
75014 Paris - France

## Manufacturer

LINITHER LIQUID MANUFACTURING  
1-3, allée de la NESTE, Zi d'en Sigal  
31770 Colomiers - France

## WHEN THIS MEDICINE SHOULD BE USED

This medicine is used for local treatment of certain types of vaginitis (infections of the vagina).

## ATTENTION!

### WHEN THIS MEDICINE SHOULD NOT BE USED

- If you are allergic to medicines in the imidazole group (the group of antibiotics that includes metronidazole), you must never use this medicine.

- If you are also taking disulfiram or consuming alcohol (alcoholic drinks, medicines containing alcohol), you should generally not use this medicine.

*IF YOU HAVE ANY DOUBTS, IT IS ESSENTIAL TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

## Special warnings

- This treatment must not be prescribed for more than 10 days and must not be given more than 2 to 3 times a year.

- You are advised not to drink any alcohol while using this medicine because of the risk of reactions such as redness of the face, hot flushes, vomiting and increased heart rate.

- You should stop using the medicine and see a doctor if you find it difficult to coordinate voluntary movements or if you feel dizzy or confused.

- If you have severe, chronic or progressive nervous disorders, special care when using this medicine.

## Precautions for use

- If you have already had blood disorders, high-dose and/or prolonged treatment, your doctor may need to carry out regular blood tests to check your complete blood count.

- If you are receiving long-term treatment with this medicine, it is important to tell your doctor if any of the following nervous disorders occur: tingling, difficulty coordinating movements, dizziness, seizures.

- Use of this pessary with condoms or diaphragms may increase the risk of the latex tearing.

*IF IN DOUBT, IT IS ESSENTIAL THAT YOU ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.*

## Drug interactions and other interactions

*TO AVOID ANY INTERACTION BETWEEN DIFFERENT MEDICINES, ESPECIALLY WITH DISULFIRAM AND ALCOHOL, YOU MUST ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU MAY BE TAKING.*

Using this medicine may affect the results of some laboratory tests (test for treponemes), as metronidazole can falsely lead to positive results for the Nelson test.

## Pregnancy - Breast-Feeding

### Pregnancy

If necessary, this medicine may be used during pregnancy. However, you must always ask your doctor or pharmacist for advice beforehand.

### Breast-Feeding

Avoid breast-feeding while using this medicine.

*AS A GENERAL RULE, DURING PREGNANCY OR BREAST-FEEDING, YOU SHOULD ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE USING ANY MEDICINE.*

## Drivers and machine operators

The attention of patients, particularly those who drive or use machines, is drawn to the risk of dizziness, confusion, hallucinations and seizures associated with this medicine.

## HOW TO USE THIS MEDICINE

### Dosage

This medicine is for use in adults only.

As a guideline, the usual dosage is:

1 pessary per day via the vaginal route, in combination with oral treatment if necessary.

It is essential for partners to be treated as well, whether or not they have any clinical signs.

*IN ALL CASES, FOLLOW YOUR DOCTOR'S PRESCRIPTION.*

## Method and route of administration

Vaginal route.

You should insert the pessary while lying down.

## Frequency and time of administration

Once a day.

The pessary should preferably be used in the evening before you go to bed.

## Treatment duration

This antibiotic will be effective only if you use it regularly at the prescribed times and for as long as your doctor advises. If fever or any other symptom disappears, it does not mean that you are cured.

Any feeling of tiredness is not caused by the antibiotic treatment but by the infection itself. Reducing or suspending treatment would have no effect on this feeling and would delay your recovery.

The duration of treatment is 7 to 10 days, depending on the condition being treated. Treatment must however not last more than 10 days and must not be given more than 2 to 3 times a year.

## Management of overdose

If you vomit, have difficulty coordinating your movements or are disorientated, consult your doctor, who may decide to prescribe treatment.

## UNWANTED AND UNPLEASANT EFFECTS

As with any active ingredient, this medicine may have effects causing varying degrees of discomfort in some patients:

- Gastrointestinal effects:

- nausea, vomiting, stomach cramps, diarrhea;
- inflammation of the tongue and dry mouth, inflammation of the mouth, metallic taste in the mouth, loss of appetite;
- in exceptional cases, pancreatitis (inflammation of the pancreas), which disappears after stopping treatment.

- Effects on the skin and mucosa:

- hot flushes with redness of the face, itching, skin rashes sometimes accompanied by fever;
- urticaria (skin rash similar to nettle rash), sudden allergic swelling of the face and neck (angioedema) and in exceptional cases, allergic shock;

- Nervous disorders:

- headache;
  - nerve impairment in the arms and legs;
  - seizures, dizziness, poor coordination of voluntary movements.
- Psychiatric disorders:
- confusion, hallucinations.
  - Blood disorders:
  - very rare cases of abnormally low white blood cell or platelet counts.

- Liver effects:

• very rare cases of abnormal liver function that is reversible, and of hepatitis resulting from biliary tract obstruction.

- Other effects:

• reddish-brown colored urine caused by the medicine.

*IF YOU NOTICE ANY UNWANTED AND UNPLEASANT SIDE EFFECTS NOT MENTIONED IN THIS LEAFLET, PLEASE INFORM YOUR DOCTOR OR PHARMACIST.*

## STORAGE

**DO NOT EXCEED THE EXPIRY DATE INDICATED ON THE OUTER PACKAGING.**

## Special precautions for storage

Do not store above 25°C.

## DATE OF LEAFLET REVISION

June 2009

## THIS MEDICAMENT

**Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.**

**Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.**

• The doctor and the pharmacist are the experts in medicines, their benefits and risks.

• Do not repeat yourself/interupt the period of treatment prescribed.

• Do not get the same prescription without consulting your doctor.

• Keep all medicaments out of reach of children.

Council of Arab Health Ministers,  
Union of Arab Pharmacists.