Package leaflet: Information for the patient
METRONIDAZOLE BP 500 mg, tablet
Metronidazole

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. What METRONIDAZOLE 500 mg tablet is and what it is used for

Metronidazole is an antibiotic and an antiprotozoal belonging to the nitroimidazole derivatives.
This medicine is indicated for the treatment of some infections due to sensitive germs (bacteria, parasites).

2. What you need to know before you take METRONIDAZOLE 500 mg tablet

Do not take METRONIDAZOLE 500 mg tablet:
- If you are allergic to metronidazole, to other imidazole derivatives (group of medicines, which metronidazole belongs to), or to any of the other ingredients of this medicine (listed in section 6).
- If the patient is younger than 6 years old.

Warnings and precautions:
Talk to your doctor or pharmacist before taking METRONIDAZOLE.
Tell your doctor is you have:
- Neurological disorders.
- Psychiatric disorders.
- Blood disorders.
- History of meningitis on metronidazole.

Tell immediately your doctor if one of the following disorders occur during the treatment with METRONIDAZOLE:
As of the first dose, there is a risk of occurrence of severe and sudden allergic reaction (anaphylactic shock, angioedema), with the following symptoms: tightness in the chest, dizziness, nausea or fainting on standing (see section “Possible side effects”). If these

symptoms occur, stop using this medicine because your life could be at risk, and contact your doctor immediately.

The occurrence, at the beginning of the treatment, of a reddening spreading to the whole body with pustules, and fever, should make one consider a severe reaction called acute generalised exanthematous pustulosis (see section “Possible side effects”); tell your doctor immediately because this requires stopping the treatment; this reaction contra-indicates any new administration of metronidazole alone or in combination with another active substance.

The potential occurrence or worsening of nervous disorders as difficulty speaking, walking, tremor, involuntary movements of the eyes, and other manifestations with the hands and feet as tingling sensation of sensation of cold, numbness, decreased sensitivity. These disorders are generally reversible with stopping the treatment. It is then important to stop the treatment and go to your doctor immediately (see section “Possible side effects”).

Behaviour disorders at risk for patients might occur as of the first doses, notably in case of history of psychiatric disorders. It is advised to stop the treatment and consult a doctor (see section “Possible side effects”).

In case of history of blood disorders, of treatment with high doses and/or prolonged treatment, your doctor might need to control regularly your blood numbering formula with blood tests.

Tell the doctor of the laboratory of analysis that you take this medicine if you have to undergo a laboratory test: taking this medicine can interfere with the results of some laboratory tests (Treponema test) given false positive results (Nelson test).

If you have Cockayne syndrome, you doctor will also monitor your liver function frequently during and after your treatment with metronidazole.

Tell your doctor immediately and stop taking metronidazole is you have the following symptoms:
- Stomach aches, anorexia, nausea, vomiting, fever, discomfort, tiredness, jaundice, dark urines, putty-coloured stools or itching.

Children
The tablets are contraindicated in children aged below 6 years old because they could choke on the tablets. Other pharmaceutical presentation exist that are more adapted to young children.

Other medicines and METRONIDAZOLE 500 mg tablet
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tell your doctor particularly if you take:
- Medicines containing alcohol because of reddening-type reactions of the face, heat, vomiting, increased heart rate.
- Busulfan (advised in the treatment of certain blood diseases and in preparation for bone marrow graft).
- Disulfiram (used in prevention of relapse of alcohol dependence).

METRONIDAZOLE with food and drink

Avoid taking alcohol containing drink during treatment of reddening-type reactions of the face, heat, vomiting, increased heart rate.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
If required, metronidazole may be taken during pregnancy. Talk to your doctor or your pharmacist before taking this drug.
It is advised not to use metronidazole if you are breast-feeding.

Driving and using machines
While taking metronidazole you may feel dizzy, confused or may have hallucinations, convulsions or troubles vision. If this happens, do not drive or use any machinery or tools.

3. How to take METRONIDAZOLE 500 mg tablet

This medicine is for adults and children older than 6 years. For children under 6 years, other pharmaceutical forms are recommended.
The dose of metronidazole will depend on your age and on the illness being treated
The usual dose is:

- in adults: 750 mg to 2 g daily
- in children: 500 mg daily to 20 to 40 mg/kg/day

In some case, your partner should absolutely also be treated regardless of the presence of clinical signs.
ALWAYS FOLLOW THE INSTRUCTIONS OF YOUR DOCTOR

Oral route.
The tablets should be swallowed with a glass of water.
The frequency of intakes may vary from one to 3 times daily depending on the indication.
For its efficacy, this drug should be taken following the posology and as long as your doctor has instructed you. If your fever decreases or if your symptoms disappear, this does not mean that your infection is cured. The feeling of fatigue is not due to your treatment but is due to your infection. Reducing or suspending your treatment will not improve this feeling but will postpone your healing.

In the following cases, the treatment duration is as follows:
lambliasis (parasitic infection): 5 days; amibiasis (parasitic infection) and some vaginitis (vaginal infection): 7 days; trichomonasis (parasitic infection): single dose treatment.

If you take more METRONIDAZOLE 500 mg tablet than you should
Consult your doctor or pharmacist immediately.
In case of vomiting, difficulties in coordinating your movements, confusion, consult your doctor.

If you forget or stop to take METRONIDAZOLE 500 mg tablet
Not applicable.

If you stop taking METRONIDAZOLE 500 mg tablet
Not applicable.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Digestion disorders:
- Digestive disorders: stomach pain, nausea, vomiting, diarrhoea.
- Tongue inflammation with sensation of dry mouth, mouth inflammation, taste perversion and loss of appetite.
- Pancreatitis (inflammation of pancreas), reversible upon treatment discontinuation.
- Discolouration or modification of the aspect of the tongue (might be caused by fungi development).

Skin and mucosa disorders:
- hot flushes with face reddening, itching, rash with sometimes fever.
- Urticaria (skin eruption similar to nettle stings), sudden swelling of the face or of the neck from allergic origin (angioedema), allergic shock that can be life-threatening (see section "What you need to know before you take METRONIDAZOLE 500 mg tablet").
- Very rare cases of reddening spreading to the whole body with pustules and fever (acute generalised exanthematous pustulosis) (see section "What you need to know before you take METRONIDAZOLE 500 mg tablet").
- Bullous eruption with skin peeling that can spread to the whole body and be life-threatening (Lyell syndrome, Stevens-Johnson syndrome).
- Fixed pigmented erythema: skin eruption with rounded red spots with itching and burning sensation leaving coloured spots and that can appear at the same locations in case of renewed administration of the medicines.

Nervous system disorders:
- Nerve damages of the limbs (sensitive peripheral neuropathies) resulting in hands and feet disorders as tingling, stinging, cold sensation, numbness sensation, decreased sensitivity?
- Headache.
- Convulsion.
- Confusion.
- Neurological disorders called encephalopathies or cerebellar syndrome, resulting in a confusion state, conscious or behaviour disorders, difficulty to coordinate movements, pronunciation disorders, walking disorders, involuntary movement of the eyes, tremor. These disorders are generally reversible upon stopping the treatment and might be associated with modification of medical imaging (MRI). Exceptionally, cases of fatal evolution have been reported (see section "What you need to know before you take METRONIDAZOLE").
- Non-microbial meningitis.

Psychic disorders
- Hallucinations.
- Personality disorders (paranoia, delirium) that can come with suicidal ideation or act (see section "What you need to know before you take METRONIDAZOLE").
- Depressive tendency

Visual disorders:
- Transient visual disorders as blurred vision, near-sightedness, decreased vision, change in the colour vision.
- Ophthalmic nerve damage/inflammation.

Blood disorders:
- Abnormally low levels of white blood cells (neutrophils) or platelets.

Liver disorders:
- Increase in hepatic enzymes (transaminases, alkaline phosphatase)
- Very rare cases of severe liver disease (sometimes with jaundice), notably cases of hepatic deficiency requiring transplantation.

Others
- Red brown urine colouration caused by the medicine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system

5. How to store METRONIDAZOLE 500 mg tablet

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the blister, pouch and box. The expiry date refers to the last day of that month.
Store below 30º C. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What METRONIDAZOLE 500 mg tablet contains
The active substance is metronidazole BP 500 mg.
The other ingredients are: maize starch, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), talc, magnesium stearate, sodium laurylsulfate, gelatine, microcrystalline cellulose, lactose, sucrose, sodium croscarmellose.

What METRONIDAZOLE 500 mg tablet looks like and contents of the pack
Blister pack of PVC-Aluminium of 10 scored tablets packaged in a paper pouch.
Box of 50 pouches.

Marketing Authorisation Holder
Exphar s.a. Zoning Industriel de Nivelles Sud, zone II – Av. Thomas Edison 105 – 1402 Thines (Belgium).

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