Package leaflet: Patient information leaflet
Metronidazole suspension 125 mg/5ml
as Metronidazole benzoate BP

Read all of 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 only. 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, talk to your doctor or pharmacist.

What is in this leaflet

1. What METRONIDAZOLE Suspension is and what it is used for

Pharmacotherapeutic group
Antibiotics, antibacterials and antiprotozoal, nitroimidazole derivatives.

Therapeutic indications
This medicine is indicated in the treatment of infections caused by organisms sensitive to nitroimidazole derivatives (bacteria, parasites).

2. What you need to know before you take METRONIDAZOLE Suspension

Do not take METRONIDAZOLE Suspension :
- 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).

Warnings and precautions
Talk to your doctor or pharmacist before taking METRONIDAZOLE Suspension.
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, 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
Not applicable

Other medicines and METRONIDAZOLE Suspension
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 Suspension 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.

METRONIDAZOLE suspension contains sucrose
This medicine contains sucrose. If you suffer from intolerance to fructose, glucose-galactose malabsorption or sucrose-isomaltase insufficiency, you should not take this medicine.
This medicine contains 2.5 g of sucrose per 5 ml. This should be taken into account if you have diabetes.

3. How to take METRONIDAZOLE Suspension

Posology and method of administration
The length of a course will depend on your age and the illness being treated.

The usual dose is:
- For adults : 0.5 g/day to 1.5 g/day
- For children: 250 mg/day to 20-40 mg/kg/day.

In some cases, your (sexual) partner should also be treated (with or without clinical signs of infection).

IN ANY CASE, REFER TO YOUR DOCTOR'S PRESCRIPTION.

Frequency of administration
2 to 3 times daily, (according to the specific indications)

Treatment duration
Always take this medicine (antibiotic) exactly as your doctor has told you (at the prescribed doses and as longer as your doctor has told you)

Take the complete treatment prescribed by your doctor, even if you begin to feel better before you have finished them all. The fatigue sensation is not caused by antibiotic therapy but it is due to the infection.
If you stop taking the treatment too soon, the infection may return or your condition may get worse.

Particular cases:
Giardiasis treatment duration is 5 days
Ameobiasis treatment duration is 7 days
Vaginitis treatment duration is 7 days
Vagitinis due to trichomonas treatment duration is 10 days

If you take more METRONIDAZOLE Suspension 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 to take METRONIDAZOLE Suspension
Not applicable.

If you stop taking METRONIDAZOLE Suspension
Not applicable.

4. Possible side effects

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

Digestive disorders
- Digestive disorders: stomach pain, nausea, vomiting, diarrhoea
- Tongue inflammation with sensation of dry mouth, mouth inflammation, taste perversion and loss of appetite.
- Pancreatitis (pancreas inflammation), 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 Suspension").
- 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 Suspension").
- 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 Suspension").
- 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 Suspension").
- Depressive tendency

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

Blood system 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 Suspension

Keep this medicine out of the sight and reach of children.
Do not use this METRONIDAZOLE Suspension after the expiry date which is stated on the bottle.The expiry date refers to the last day of that month.
Store below30 °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 Suspension contains
The active substance is metronidazole 125 mg/5ml as metronidazole benzoate BP
The other ingredients are: sodium benzoate (E211), carmellose sodium, sodium methyl hydroxybenzoate (E219), sodium propyl hydroxybenzoate (E217), guar gum, disodium edetate, polysorbate 80, aspartame (E951), citric acid, colloidal anhydrous silica, essence raspberry, sucrose, tartrazine supra (E102), purified water.

What METRONIDAZOLE Suspension looks like and contents of the pack
This medicine is presented in oral suspension. Bottle of 100 ml.

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

Manufacturer:
Gracure Pharmaceuticals Ltd.
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