

NEO-PENOTRAN PESSARY

Metronidazole (500mg), Miconazole Nitrate (100mg)

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What NEO-PENOTRAN is used for

NEO-PENOTRAN is used for the treatment of vaginal inflammation (vaginitis) with symptoms like itching, burning, abnormal discharge, swelling and redness in vagina.

How NEO-PENOTRAN works

NEO-PENOTRAN is a product in a bullet form (pessary) that is applied by placing it into the vagina. It belongs to the group of drugs named antibacterial (effective against bacteria), antiprotozoal (effective against parasites), antifungals (effective against fungal diseases).

Before you use NEO-PENOTRAN

- When you must not use it

Do not use NEO-PENOTRAN if you are allergic (hypersensitive) to any of the ingredients in this product (see composition list)

- Before you start to use it

Please inform your doctor or pharmacist before using this medicine if:

- You consume alcohol on a regular basis.
- You have or have ever had a liver problem
- You have a disease of the nervous system
- You are having kidney dialysis
- You are pregnant, or may become pregnant
- You are breast-feeding.

- Taking other medicines

You should always tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription:

- Drugs that make your blood thinner (oral anti-coagulants)
- Anti-epileptics (phenytoin, phenobarbital)
- Drug reducing stomach acid (cimetidine)
- Anti- diabetes medicine (glimepiride)
- Anti-asthma medicine (theophylline)
- Anti-allergic medicines (astemizole and terfenadine)
- Drug for cardiac rhythm disorders (amiodarone and procainamide)
- Drug for the suppression of immune system (cyclosporine)
- Drug for urinary incontinence or leakages (oxybutynin and tolterodine)
- A drug for the treatment of alcoholism (disulfiram)
- A drug against psychosis and depression (lithium)
- Drug for treatment of epilepsy (carbamazepine, phenytoin and phenobarbital)

Results of the laboratory tests may change while you use NEO-PENOTRAN as interference with levels of liver enzymes, glucose (hexokinase method), theophylline,

and procainamide have been observed. Please remind your doctor that you are taking NEO-PENOTRAN if you need to undergo blood tests while using it.

How to use NEO-PENOTRAN

- How much to use

Do not use without consulting a physician. If it is not advised otherwise by a physician, one pessary should be inserted high into the vagina at night for 14 days or one pessary at night and one in the morning for 7 days. In recurrent cases, one pessary should be inserted high into the vagina at night and in the morning for 14 days.

For elderly patients (over 65 years): Same dose as for younger adults.

Children: Not recommended for children.

Not to be swallowed or not to be applied by other routes.

It is not recommended that the administration of NEO-PENOTRAN in the menstrual period because of the impaired efficacy of the product or facing some difficulties during administration.

- When to use it

NEO-PENOTRAN is only applied into the vagina.

NEO-PENOTRAN should not be swallowed or administered by another route.

Wash your hands thoroughly before applying the drug. Lie back before applying the drug. Slightly draw your legs upwards. Place one pessary into the vagina and push it as

deep as possible. After application, wash your hands thoroughly and if possible lie down so as to not stand up for half an hour.

- How long to use it

Use NEO-PENOTRAN for the duration of time your doctor or pharmacist recommends.

- If you forget to use it

Do not administer double dose to compensate for the forgotten doses. Consult your doctor or pharmacist if you have any doubts.

- If you use too much (overdose)

If you have used more NEO-PENOTRAN than you needed, contact your doctor or hospital immediately. If possible, show them the remaining medicine. Medical treatment may be required.

While you are using it

- Things you must do

Follow the instructions for the administration of NEO-PENOTRAN exactly as your doctor tells you. Ask your doctor or pharmacist if you have any doubts.

- Things you must not do

You must not take alcohol during the therapy and for at least 24-48 hours after the end of course of treatment because of the possibility of increased alcohol incompatibility. You must not use the pessary together with the contraceptive diaphragms and condoms since the vaginal pessary base may affect the rubber, which may possibly break.

Do not stop using NEO-PENOTRAN unless told to do so by your doctor.

Do not use NEO-PENOTRAN to treat any other conditions unless your doctor tells you to.

Do not give or recommend NEO-PENOTRAN to anyone else, even if they have the same condition as you.

- Things to be careful of

Driving and using machines

NEO-PENOTRAN has no known influence on the ability to drive and use machines as long as used in dose and duration suggested by your doctor. However, if you sense any side effects like dizziness, tiredness, weakness, do not drive or use machines.

Side effects

Like all drugs, NEO-PENOTRAN can produce adverse effects, although not everyone suffers from them.

NEO-PENOTRAN may cause side effects on cardio-vascular, central nervous system, gastrointestinal and skin reactions.

Stop using NEO-PENOTRAN and seek medical assistance immediately if you experience any of the following symptoms:

Very Serious Side Effects:

- Serious skin rashes
- Swelling in the face, lips, tongue and throat, shortness of breath

If you have one of these, it means that you are allergic to NEO-PENOTRAN. You might need urgent medical attention or hospitalization.

All of these very serious side effects are considerably rare.

If you notice any one of the following, consult your doctor or pharmacist of the nearest hospital immediately:

Severe Side Effects:

- Seizures like epilepsy (convulsions)
- Walking like you are drunk (ataxia)
- Mental changes, depression
- Weakness, pain, tingling at hands and feet (peripheral neuropathy symptoms)
- Decrease in white blood cells (leukopenia)
- Headache, dizziness
- Tiredness or weakness
- Taste changes, metallic taste
- Dry mouth, thirst
- Nausea, vomiting, loss of appetite
- Abdominal pain or cramp
- Intestinal obstruction or diarrhoea

These are all severe side effects. May require emergency medical attention. Severe side effects occur very rarely.

If you notice any of the following, inform your doctor:

Mild Side Effects:

- Burning, itching, irritation, discharge, skin rash
- Abdominal pain

These are mild side effects of NEO-PENOTRAN.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of NEO-PENOTRAN

- Storage

Keep this medicine out of the sight and reach of children.
Store below 30°C.

Do not use this medicine after the expiry date.

- Disposal

If your doctor tells you to stop using NEO-PENOTRAN or your NEO-PENOTRAN have passed their expiry date, ask your pharmacist or doctor what to do with any that are left over.

Do not simply throw the leftover or expired products into the dustbin.

Product Registration Holder

Eurodrug Laboratories (M) Sdn Bhd
T2-21-10, The Square,
One City, Jalan USJ 25/1C,
47650 Subang Jaya,
Selangor, Malaysia.

Date of Revision

30/01/2023

Serial Number

NPRA (Rx/x)xxxxxx/xxxxx

Product Description

- What it looks like

White bullet-shaped pessary.

- Ingredients

- *Active Ingredients:*

Metronidazole, Miconazole
nitrate

- *Inactive Ingredient:*

Hard fat

- MAL number

MAL20032405AZ

Manufacturer

Exeltis Ilac San. Ve Tic. A.S.
Cerkezkoy Organize Sanayi
Bolgesi, Gaziosmanpasa
Mahallesi, Fatih Bulvari,
No:19/2 Cerkezkoy-Tekirdag,
Turkey.