

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### NEO-PENOTRAN FORTE

750 mg + 200 mg vaginal suppository

METRONIDAZOLE, MICONAZOLE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •*

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#### What is in this leaflet?

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3. How to take Neo-Penotran Forte
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#### 1. WHAT NEO-PENOTRAN FORTE IS AND WHAT IT IS USED FOR

Neo-Penotran Forte is a preparation in form of vaginal suppositories, which are administered by placing into the vagina. It belongs to a group of medicines called antibacterial (effective against bacteria), antiprotozoal (effective against parasites), antifungal agents (effective against fungal diseases).

Each vaginal suppository is whitish-yellow in color and contains active ingredients metronidazole 750 mg and miconazole nitrate 200 mg. Medicine Neo-Penotran Forte is available in a package that contains 7 vaginal suppositories.

Neo-Penotran Forte is used to treat inflammation of the vagina (vaginitis) with symptoms such as itching, tingling, abnormal discharge, redness and swelling of the vagina.

#### 2. BEFORE YOU TAKE NEO-PENOTRAN FORTE

##### **Do not use Neo-Penotran Forte:**

- If you are allergic to any of the active substances and/or any of the auxiliary substances in the composition of the medicinal product,
- If you are in the first trimester of pregnancy,

- If you have Porphyria (genetic, metabolic disorder of the blood system),
- If you have epilepsy,
- If you have serious disorder of liver function.

Alcohol must not be consumed during treatment or at least 3 days after the end of treatment with Neo-Penotran Forte.

Medicines used in the treatment of alcoholism and which as an active ingredient contain a substance called Disulfiram should not be used during treatment with Neo-Penotran Forte or within 2 weeks after treatment.

***Be especially careful with with Neo-Penotran Forte in the following cases***

- Medicine Neo-Penotran Forte can cause damage to rubber. Therefore, avoid contact with contraception or diaphragms that are used for birth control. Otherwise, you may experience an side pregnancy.
- in some cases it may be necessary to treat your husband with corresponding orally applied medicine. If your doctor determined this way, strictly follow the therapy that is prescribed to you and to your husband.
- If this medicine is applied in a larger dose and for longer periods of time than suggested by your doctor, you may experience weakness, pain, paraesthesia, tingling in the arms and legs (peripheral neuropathy symptoms) and seizures similar to epilepsy. In this case, stop using the medication and contact your doctor or go to a hospital immediately.

Do not use other vaginal products (such as tampons, rinse aid and vaginal preparations that kill sperm (spermicide)) during treatment with Neo-Penotran Forte.

Medicine Neo-Penotran Forte should not be used in virgins and young girls who are not sexually mature.

Please consult your doctor, even if these statements were applicable to you at some point in the past.

***Taking other medicines with Neo- Penotran Forte***

Inform your doctor or pharmacists if you consume alcohol or use one of the medications which are listed below:

- medications to prevent blood clotting (for example: medicines as active substances contain acenocoumarol, anisindion, dikumarol, fenindion, phenprocoumon and warfarin)
- medicines used to treat gastrointestinal ulcers and that as the active ingredients they contain substances that are referred to as cimetidine and Cisapride
- medicines used for the treatment of allergic diseases (for example: medicines as active substances contain Astemizole and life)
- medicines for Suppression of the immune system, which as an active ingredient they contain a substance called Cyclosporine
- medicines used to treat diabetes and who as an active ingredient they contain a substance called glimepiride
- medicines used to treat problems such as urinary incontinence, frequent urination (thamuria), urine flow (for example: medicines that contain active substances like Oxybutynin and tolterodin)
- medicines used for the treatment of mental disorders and who as an active ingredient they contain a substance called pimozide
- medicines used to treat alcoholism and who as an active ingredient they contain a substance called Disulfiram
- medicines used for the treatment of cancer (for example: medicines that contain active substances such as fluorouracil and trimetrexate)
- medicines used to treat epilepsy (for example: medicines as active substances include carbamazepine, fosfenitoin, phenobarbital and phenytoin)

- medicines used for the treatment of affective disorders and who as an active ingredient they contain a substance called lithium
- medicines that have a narcotic effect and which contain active substances that are referred to as oxycodone and fentanyl, which is specially used as analgesics for overcoming severe pain in patients with cancer
- medicines used to treat asthma and who as an active ingredient they contain a substance called theophylline
- medicines used to treat abnormal heart rhythms, and that as the active ingredients they contain substances which are called amiodarone and procainamide

If you are currently using or have recently used any other medicines, including medicines that are issued without a prescription, please tell your doctor or pharmacist.

### ***Taking food and drinks with Neo- Penotran Forte***

Neo-Penotran Forte has no interactions with the food.

### ***Pregnancy***

Talk to your doctor or to the pharmacist before using this medicine.

If you are pregnant, only your doctor can decide whether to use Neo-Penotran Forte or not.

If during the treatment, you notice that you are pregnant, talk to your doctor or pharmacist.

### ***Breast feeding***

Talk to your doctor or pharmacist for advice before using this medicine.

Metronidazole, as one of the active substances of the medicinal product Neo-Penotran Forte appears in human milk. Therefore, breastfeeding should be discontinued during treatment and started again 24-48 hours after the end of treatment.

### ***Driving and using machines***

Neo-Penotran Forte has no known effects on ability to drive and use machine as long as it is used according to the dosage and the duration prescribed by your doctor. However, if you experience any side effects, such as dizziness, fatigue, weakness, do not drive or use the machines.

Important information about some of the auxiliary substances contained in Neo-Penotran Forte  
Neo-Penotran Forte has no auxiliary substances that require a special alert.

## ***3. HOW TO USE NEO-PENOTRAN FORTE***

Instructions for the proper use and dosage/frequency of administration

Unless your doctor has not advised differently, begin by applying a single vaginal suppository once a day, in the evening before going to sleep during 7 days. In case of the return of disease, a doctor may recommend a single vaginal suppository at night (preferably in the evening when you go to sleep) during 14 days.

We do not recommend use of Neo-Penotran Forte during menstruation due to reduced effectiveness of the medicine or certain difficulties during the application.

### ***The method and route of administration:***

Neo-Penotran Forte applies only in the vagina.

Please thoroughly wash and dry your hands. Lie down on your back before administration of the medicine. Slightly lift your legs up. Insert a suppository into the vagina and push it as deeper as possible. After application wash your hands thoroughly again and if possible don't get up half an hour after that.

**Different age groups:**

Use in children:

Neo- Penotran Forte should not be used in children younger than 12 years.

**Use in elderly:**

There is no particular recommendation for the elderly.

**Special applications:**

Renal failure: there are no special instructions for use. If you are a patient on dialysis, you must contact your doctor before beginning treatment with Neo-Penotran Forte.

Liver failure: If you have liver failure, Neo-Penotran Forte has to be carefully applied, and under the supervision of your doctor. In this case, your doctor will adjust the dose of Neo-Penotran Forte.

If you have the impression that the effect of Neo-Penotran Forte is too strong or too weak, talk to your doctor or pharmacist.

If you use more Neo-Penotran Forte than you should

If you have used more than you should, you should talk to a doctor or pharmacist.

When dose is exceeded, you may experience vomiting, nausea, lack of appetite, abdominal pain, diarrhea, itching, metallic taste in the mouth, walking like you're drunk (ataxia), headache, dizziness, epilepsy-like seizures (convulsions), a reduction in the number of white blood cells (leucopenia), a dark color of the urine, burning sensation in the mouth and throat, burning sensation in the hands and feet, tingling, numbness and prickling sensation (paraesthesia). In this case, contact your doctor or go to a hospital immediately.

**If you forget to use the remedy of Neo-Penotran Forte**

Do not use a double dose to make up for a forgotten dose.

**If you stop using the medicine of Neo-Penotran Forte**

If the therapy is interrupted before the time, vaginitis can be back and the symptoms of vaginitis reappear. No negative effect is expected when therapy with Neo-Penotran Forte is interrupted after the completion of the application, which is advised by your doctor.

#### 4. Possible side effects

As with any medicine, side effects can occur in people who are sensitive to the ingredients of the Neo-Penotran Forte.

If any of the following occurs, stop using Neo-Penotran Forte and immediately inform your doctor or go to the nearest hospital emergency room:

- serious skin rashes
- swelling of the face, lips, tongue and throat, shortness of breath

These are all very serious side effects.

If you have any of these side effects, it means that you are allergic to the medicine Neo-Penotran Forte. You may need urgent medical attention or hospitalization.

All of these very serious side effects are considerably rare.

If you notice any of the following, contact your doctor or go to the nearest hospital emergency room:

- attacks similar to epilepsy (seizures), coma

- walking like you're drunk (ataxia)
- mental changes, depression
- weakness, pain, stinging, tingling in the arms and legs (peripheral neuropathy symptoms)
- a reduction in the number of white blood cells which can be determined by using a full blood count, which indicates an infection in the body (leucopenia)
- the headache, dizziness
- tiredness or weakness
- changes flavor, metallic taste
- dry mouth, thirst
- the nausea, vomiting, loss of appetite
- the pain or cramping
- bowel obstruction or diarrhea

It is less likely to have these side effects occur when applying a vaginal suppository, since metronidazole appears less in the blood with intravaginal application.

Severe side effects occur very rarely.

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

- burning, itching, irritation, vaginal discharge, skin rash in the area of application of the
- abdominal pain

These are the mild side effects of the medicine Neo-Penotran Forte.

### **Reporting of side effects**

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **5. HOW TO STORE NEO-PENOTRAN FORTE**

Keep out of the reach and sight of children and keep it in its original packaging.

Store at room temperature up to 25 ° c.

Use in accordance with the expiration date.

Do not use Neo-Penotran Forte after the expiry date listed on the package.

Do not use Neo-Penotran Forte if you notice damage of the medicine and/or packages.

### **6. FURTHER INFORMATION**

- Active substances: every vaginal suppository contains 750 mg of metronidazole and 200 mg of miconazole nitrate.
- Auxiliary substance: Witepsol

### **Regime of dispensing**

The medicine is issued on doctor's prescription

### **Manufacturer**

Bayer Pharma AG  
13342 Berlin, Germany

***Manufacturer of the medicinal product***

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