# PACKAGE LEAFLET

**NOVO-VULOTRAN FORTE L Vaginal Suppository**
**To be inserted into the vagina.**

- ***Active substances:*** Each ovule contains 750 mg metronidazole, 200 mg miconazole nitrate and 100 mg lidocaine.
- ***Excipients:*** Polyethylene glycol 1000, witepsol.

***Read all of this PACKAGE LEAFLET carefully before you start using 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. Do not pass it on to others.*
- *During the period when you use this medicine, tell your doctor that you use this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not use either a **higher** or **a lower** dose other than recommended to you for this medicine.*

**In This Leaflet:**



## 1. WHAT NOVO-VULOTRAN FORTE L IS AND WHAT IT IS USED FOR

- NOVO-VULOTRAN FORTE L is a preparation in the form of vaginal ovules, which are applied by placing into the vagina. It belongs to a group of medicines called antibacterial (effective against bacteria) and antifungal (effective against fungal diseases) agents.
- The whitish-yellow colored, homogenous-looking, ellipsoid-shaped ovule contains 750 mg metronidazole, 200 mg miconazole nitrate and 100 mg lidocaine as active substances. NOVO-VULOTRAN FORTE L is supplied in packages of 7 ovules accompanied by 7 finger covers for use when inserting the medicine into the vagina.
- NOVO-VULOTRAN FORTE L is used to treat inflammation of the vagina (vaginitis) caused by bacteria with symptoms such as itching, burning, abnormal discharge, redness and swelling of the vagina.

## 2. BEFORE YOU USE NOVO-VULOTRAN FORTE L

**Do not use NOVO-VULOTRAN FORTE L in the following situations:**
- If you are allergic (hypersensitive) to any of the active substances of NOVO-VULOTRAN FORTE L or their derivatives
- If you are in the first 3 months of your pregnancy
- If you have porphyria disease (a hereditary, metabolic disorder of the blood system)
- If you have epilepsy,
- If you have severe liver dysfunction.

Do not consume alcohol during treatment with NOVO-VULOTRAN FORTE L and within the first 48 hours after the treatment ends.

Do not use any medicine used against alcohol addiction and containing disulfiram as active substance during NOVO-VULOTRAN FORTE L treatment and for 2 weeks after treatment.

**Take special care with NOVO-VULOTRAN FORTE L in the following situations:**

- NOVO-VULOTRAN FORTE L may cause damage to latex. Therefore, avoid contact of ovules with latex-containing condoms or diaphragms used for birth control. Otherwise unwanted pregnancies may occur.
- In some cases, your partner also may need treatment with orally taken drugs. If your doctor determines such a condition, exactly comply with the therapy given you and your partner.
- If used in higher doses and for a longer period other than prescribed to you by your doctor, you may experience side effects such as weakness in your hands and feet, pain, numbness, tingling sensation (symptoms of peripheral neuropathy) and epilepsy-like seizures (convulsion). If these occur, stop using the drug and go to your doctor or to a hospital.
- If you have or have ever had liver disease.
- If you are receiving dialysis due to kidney failure.
- If you have a disease related to your nervous system.
- Alcoholic beverages should be avoided during treatment. You should not consume alcohol for 48 hours after the treatment.
- You should use metronidazole with caution if you have a blood-related genetic disease in your medical history.
- Lidocaine may cause irregular heartbeat, difficulty breathing, coma, even death if applied in large skin areas and especially if covered with bandages. These effects are not probable as NOVO-VULOTRAN FORTE L is used as ovule and following the instruction in "Instructions for proper use and dose/frequency of administration". Follow the dose and administration period your doctor has recommended exactly.
- If severe irritation occurs at the application area due to the use of NOVO-VULOTRAN FORTE L, stop using the drug and go to your doctor or to a hospital.
- Do not use tampons during treatment with NOVO-VULOTRAN FORTE L.
- Do not use any other vaginal products (such as tampons, douche, spermicidal effective products etc.) during treatment with NOVO-VULOTRAN FORTE L.

NOVO-VULOTRAN FORTE L should not be used in sexually immature girls and virgins.

Cases of serious liver toxicity/acute liver failure, including cases with fatal outcome, have been reported with metronidazole-containing products in patients with Cockayne syndrome. If you are affected by Cockayne syndrome, your liver function should also be monitored frequently by your doctor during and after your treatment with metronidazole.

Cases of severe bullous skin reactions, such as Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), or acute generalized exanthematous pustulosis (AGEP), have been reported with metronidazole. If symptoms or signs of SJS, TEN or AGEP are present, NOVO-VULOTRAN FORTE L treatment should be discontinued immediately.

If these warnings apply to you, even at any time in the past, please consult your doctor.

**Using NOVO-VULOTRAN FORTE L with food and drink**
NOVO-VULOTRAN FORTE L does not interact with food and drinks due to its method of administration.

**Pregnancy**
*Consult your doctor or pharmacist before using this medication.*

If you are pregnant, only your doctor can decide whether you can use NOVO-VULOTRAN FORTE L.

*If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

**Breastfeeding**
*Consult your doctor or pharmacist before using this medication.*

Metronidazole, one of the active ingredients of NOVO-VULOTRAN FORTE L, passes into breast milk. Therefore, breast-feeding should be discontinued during treatment and continued 24-48 hours after the end of treatment.

**Driving and using machines**
If taken in doses and period as recommended by your doctor, NOVO-VULOTRAN FORTE L has no known effect on the ability to drive and use machines. However, if you experience side effects such as dizziness, tiredness and weakness during treatment with NOVO-VULOTRAN FORTE L, do not drive or use machines.

**Important information regarding some excipients in NOVO-VULOTRAN FORTE L**
NOVO-VULOTRAN FORTE L contains no ingredient that requires special warning.

**Concomitant use with other medicines**
Tell your doctor or pharmacist if you are especially consuming alcohol or taking any of the following medicines:

- Drugs used to prevent blood clots (e.g. drugs containing active substances such as acenocoumarol, anisindione, dicumarol, fenindione, fenprocumone and warfarin)
- Drugs used in the treatment of stomach and duodenal ulcers and containing cimetidine and cisapride as the active ingredients
- Drugs used in the treatment of allergic diseases (e.g. drugs containing astemizole and terfenadine as the active substances)
- Drugs that suppress the immune system and contain cyclosporine as the active substance
- Veruconium, used as a muscle relaxant,
- Drugs used in the treatment of diabetes and containing glimepiride as the active substance
- Cholestyramine, used to reduce the level of blood fats,
- Ergot alkaloids used to reduce migraine headaches and bleeding in the uterus after surgery
- Drugs used in the treatment of problems such as urinary incontinence, frequent urination and urine leakage (e.g. drugs containing oxybutynin and tolterodine as the active substances)
- Drugs used in the treatment of mental disorders and containing pimozide as the active substance

- Drugs used in the treatment of alcohol dependence and containing disulfiram as the active substance
- Drugs used in the treatment of cancer (e.g. drugs containing fluorouracil, trimetrexate and busulfan as the active substances)
- Drugs used in the treatment of epilepsy (e.g. drugs containing carbamazepine, fosphenytoin, phenobarbital and phenytoin as the active substances)
- Drugs used in the treatment of affective disorders and containing lithium as the active substance
- Drugs containing active substances oxycodone and fentanyl, which are narcotic drugs and are used as painkillers in the treatment of very severe pain, especially in cancer patients.
- Drugs used in the treatment of asthma and containing theophylline as the active substance
- Drugs used in the treatment of irregular heartbeat and containing amiodarone and procainamide as the active substances
- Drugs used in the treatment of high blood pressure (hypertension) and heart diseases, and containing propranolol as the active substance
- Drugs used in the treatment of cardiac arrhythmias (antiarrhythmic drugs)
- Drugs used as sedatives and included in the drug group called barbiturates

*Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.*

## 3. HOW TO USE NOVO-VULOTRAN FORTE L

**Instructions for proper use and dose/frequency of administration:**
Unless recommended otherwise by your doctor, at the beginning of the treatment, apply 1 ovule once a day for 7 days before going to bed. In case of recurrence of the disease, your doctor may recommend you to use 1 ovule in the evening (preferably at bedtime) for 14 days.

It is recommended not to use NOVO-VULOTRAN FORTE L during menstrual periods as its effect may decrease or difficulty in use may occur.

**Method and route of administration:**
NOVO-VULOTRAN FORTE L is used only by inserting into the vagina.

Wash and dry your hands thoroughly before inserting the ovule. Lie on your back. Pull your legs to you and a little upward. Put one of the finger covers over your finger and insert the ovule with this finger into your vagina as deep as you can. Wash your hands again and, if possible, lie down for at least half an hour after the application.

Follow the treatment period determined by your doctor.

NOVO-VULOTRAN FORTE L should not be swallowed or administered by any other route.

**Different age groups:**
Use in children:
NOVO-VULOTRAN FORTE L should not be given to children below 12 years of age.

Use in elderly:
There is no special recommendation for use in the elderly.

**Use in special conditions:**
Kidney impairment:
There are no special recommendations for use. If you are a patient on dialysis, you should consult your doctor before starting NOVO-VULOTRAN FORTE L treatment.

Liver impairment:
If you have liver impairment, you should use NOVO-VULOTRAN FORTE L carefully and under supervision of your doctor. In this case, your NOVO-VULOTRAN FORTE L dose will be adjusted by your doctor.

*If you have an impression that the effect of NOVO-VULOTRAN FORTE L is too strong or too weak, please contact your doctor or pharmacist.*

**If you used more NOVO-VULOTRAN FORTE L than you should:**
*Talk to a doctor or pharmacist if you have used more NOVO-VULOTRAN FORTE L than you should.*

If you exceed the recommended dose; nausea; vomiting; loss of appetite; abdominal pain; diarrhea; itching; metallic taste in the mouth; abnormal gait like drunk (ataxia); headache; dizziness; epilepsy-like seizures (convulsions); a reduction in white blood cell count (leucopenia); darker urine color; burning sensation in the mouth and throat; burning, tingling, numbness and prickling sensations (paresthesia) in the arms and legs; irregular heartbeat; difficulty breathing; coma or even death may occur. In such a case and if NOVO-VULOTRAN FORTE L is accidentally swallowed in large quantities, contact your doctor or a hospital immediately.

**If you forget to use NOVO-VULOTRAN FORTE L:**
*Do not take a double dose to make up for a forgotten dose.*

**Effects that may occur when treatment with NOVO-VULOTRAN FORTE L is terminated:**
If treatment is terminated prematurely, vaginitis may recur and symptoms of vaginitis may reappear. No adverse effects are expected when NOVO-VULOTRAN FORTE L treatment is terminated after it has been administered for the period recommended by your doctor.

## 4. POSSIBLE SIDE EFFECTS
Like all medicines, side effects can occur in persons who are sensitive to the ingredients of NOVO-VULOTRAN FORTE L.

**If you notice any of the following, stop using NOVO-VULOTRAN FORTE L and IMMEDIATELY tell your doctor or go to the emergency room of the nearest hospital:**
- If you experience swelling in your hands, feet, joints, face, lips, or throat, which may cause difficulty breathing or swallowing, or if you also experience an itchy rash. These conditions indicate that you have developed an allergic reaction to NOVO-VULOTRAN FORTE L.
- A type of brain disease called encephalopathy is another severe but very rare effect. Symptoms vary, but you may experience fever, stiff neck, headache, or hear non-existent sounds. You may also have difficulty in speaking or using your hands and feet, or you may

feel dizzy.
- If you experience stomach pain, anorexia, nausea, vomiting, fever, weakness, tiredness, jaundice, dark urine, paste or mastic colored stools or itching.

All of these are considered very serious side effects.
If you develop any of these, it means you are severely allergic to NOVO-VULOTRAN FORTE L. You may need emergency medical intervention or hospitalization.
These very serious side effects are experienced very rarely.

**If you notice any of the following, inform your doctor right away or go to the emergency room of the nearest hospital:**
- Symptoms such as weakness, heart flutter, difficulty breathing and cyanosis which are seen due to lack of oxygen in the tissues (symptoms of methemoglobinemia)
- Irregular heartbeats (arrhythmia), severe difficulty breathing and severe pain in the chest, water retention in the body (edema), facial flush
- Drop in blood pressure, slowing of heartbeat (bradycardia), decrease in blood pressure (hypotension)
- Yellowish appearance on skin and eyes. This may indicate a liver disease (jaundice). Cases of liver failure requiring liver transplantation have been reported in patients treated with metronidazole in combination with other antibiotics.
- Unexpected infections, mouth sores, bruises, bleeding gums or fatigue. This may occur due to a blood problem.
- Severe pain in the stomach radiating to your back (pancreatitis)

These are all serious side effects that may require immediate medical attention.
Since metronidazole and lidocaine pass into the blood in smaller amounts when administered vaginally, the likelihood of these side effects is much lower when using ovules.
Serious side effects occur very rarely.

Side effects are listed as shown in the following categories:

| | |
|---|---|
| Very common: | may affect at least 1 in 10 patients. |
| Common: | may affect less than 1 in 10 patients but more than 1 in 100 patients. |
| Uncommon: | may affect less than 1 in 100 patients, but more than 1 in 1,000 patients. |
| Rare: | may affect less than 1 in 1,000 patients. |
| Very rare: | may affect less than 1 in 10,000 patients. |
| Not known: | cannot be estimated from the available data. |

**Tell your doctor if you experience any of the following:**
***Very common***
- Vaginal discharge

***Common***
- Inflammation of the vagina (vaginitis), vulvovaginal irritation, pelvic discomfort

***Uncommon***
- Feeling of thirst

***Rare***
- Burning, itching and irritation in the vagina, pain in the abdomen, skin rashes,

hypersensitivity reactions, and in severe cases anaphylaxis (allergic reactions) may occur.

***Very rare***
- Seizures
- Rash and redness on the skin
- Mental problems such as feeling dizzy and hearing or seeing things that do not exist (hallucinations)
- Abnormal gait like a drunk (ataxia)
- Eye problems such as blurred or double vision, decreased visual acuity, and change in color vision
- Dark colored urine
- Drowsiness or dizziness
- Pain in muscles or joints

***Not known***
- Local irritation and tenderness
- Contact dermatitis
- Hearing loss or impairment, tinnitus
- Urticaria
- Depressive mood
- Numbness, tingling, pain or fatigue in the arms and legs
- Unpleasant taste in mouth
- Rusty taste sensation in tongue
- Nausea, vomiting, stomach discomfort, constipation or diarrhea
- Loss of appetite
- Fever
- Eye pain
- Coexistence of symptoms such as fever, headache, neck stiffness, extreme sensitivity to light, nausea and vomiting. This may be caused by inflammation of the membrane surrounding the brain and spinal cord (meningitis).
- Stevens-Johnson syndrome (skin peeling with painful swelling and redness of the skin), toxic epidermal necrolysis (disorder seen with blistering and flaking of the skin)
- Burning, tingling, numbness and prickling sensation usually seen in the legs (paresthesia symptoms)
- Weakness, pain, numbness, tingling in hands and feet (symptoms of peripheral neuropathy)
- Decrease in the number of white blood cells (leukopenia), which can be determined by complete blood count and is a sign of infection in the body

These are mild side effects of NOVO-VULOTRAN FORTE L.

*If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE NOVO-VULOTRAN FORTE L

*Keep NOVO-VULOTRAN FORTE L out of the reach and sight of children and in its package.*
Store at room temperature below 25°C.

**Use in accordance with the expiry date.**
*Do not use NOVO-VULOTRAN FORTE L after the expiry date, which is stated on the package.*

Do not use NOVO-VULOTRAN FORTE L if you notice any defect on the package and/or the product.

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.

**Marketing Authorization Holder**
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

**Manufacturer**
DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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