

Package leaflet: Information for the user

Arilin[®] Rapid vaginal suppositories
1000 mg metronidazole per vaginal suppository.

For use in adults.

Read the entire package leaflet carefully before you start using this medicine because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this package leaflet. See section 4.

What is in this package leaflet

1. What is Arilin Rapid vaginal suppository and what is it used for?
2. What should you consider before using Arilin Rapid vaginal suppository?
3. How to use Arilin Rapid vaginal suppository?
4. What side effects are possible?
5. How to store Arilin Rapid vaginal suppositories?
6. Contents of the package and further information

1. What is Arilin Rapid vaginal suppository and what is it used for?

Arlin Rapid vaginal suppository is an antibiotic (a drug against bacteria) from the group of nitroimidazoles in the form of vaginal suppositories for vaginal use to treat bacterial infections.

Arlin Rapid vaginal suppository is used for:

- Trichomoniasis
- Bacterial vaginosis (amine colpitis, nonspecific colpitis)

Explanations:

Trichomoniasis is a disease caused by a flagellate, *Trichomonas vaginalis*. It mainly leads to inflammation of the vagina and the male urethra. The spread occurs almost exclusively through sexual intercourse. A secretion swab is made to detect the disease.

In bacterial vaginosis, the bacterial composition that naturally occurs in the vagina is altered. This leads to a discharge with a fish-like odor. Amine colpitis and nonspecific colpitis are other terms for bacterial vaginosis.

2. What should you consider before using Arilin Rapid vaginal suppositories? Arilin Rapid vaginal suppositories must not be used,

- if you are allergic to metronidazole, other 5-nitroimidazoles, soy, peanuts, or any of the other ingredients of Arilin Rapid vaginal suppositories listed in section 6.

- in children and adolescents under 18 years of age.

Warnings and precautions

Please talk to your doctor or pharmacist before using Arilin Rapid vaginal suppositories.

Special caution is required when using Arilin Rapid vaginal suppositories in cases of severe liver damage, blood formation disorders, and diseases of the brain, spinal cord, and nerves. Here, the treatment must be carefully considered by your doctor.

Cases of severe hepatotoxicity/acute liver failure, including cases with fatal outcomes, have been observed in patients with Cockayne syndrome with drugs containing metronidazole.

If you suffer from Cockayne syndrome, your doctor should frequently monitor your liver function during and after treatment with metronidazole.

Inform your doctor immediately and discontinue the use of metronidazole if you develop the following symptoms:

- Abdominal pain, anorexia, nausea, vomiting, fever, malaise, fatigue, jaundice, dark urine, light gray or white stool, or itching.

As with other nitroimidazole-containing drugs, treatment with Arilin Rapid vaginal suppositories should generally not exceed 10 days. This period should only be exceeded in individual cases with particularly strict indication. Appropriate monitoring of the patient (clinical monitoring and laboratory tests) is required. The treatment should only be repeated in justified individual cases. See also Chapter 3 "How to use Arilin Rapid vaginal suppositories?"

In trichomoniasis, the sexual partner is often also a carrier of trichomonads, even if no pathological changes have been noticed so far. Therefore, in trichomoniasis, it is necessary to treat the sexual partner with metronidazole as well, otherwise reinfection (recontamination) may occur. Please also avoid sexual intercourse during treatment.

Children

Arlin Rapid vaginal suppositories should not be used in children and adolescents under 18 years of age.

Use of Arilin Rapid vaginal suppositories with other medicines

Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines, even if they are non-prescription medicines.

About 20% of the active ingredient enters the bloodstream when using Arilin Rapid vaginal suppositories. Therefore, the same interactions are listed below as are possible with an oral metronidazole-containing drug.

Which other medicines affect the action of Arilin Rapid vaginal suppositories?

The administration of the alcohol withdrawal drug disulfiram can lead to confusion and certain mental disorders (psychoses).

A reduction in the effect of Arilin Rapid vaginal suppositories occurs with the administration of

Barbiturates (medicines with active ingredients such as hexobarbital or phenobarbital, used for sleep disorders and seizures as well as in anesthesia) and with the administration of medications with phenytoin (active ingredient against seizures).

Medicines with cimetidine (active ingredient against gastritis and stomach and intestinal ulcers) can, in individual cases, impair the excretion of metronidazole (active ingredient of Arilin Rapid vaginal suppositories) and thus enhance the effect of Arilin Rapid vaginal suppositories.

Which other medicines are affected in their action by Arilin Rapid vaginal suppositories?

Which other medications are affected in their action by Arilin Rapid vaginal suppositories?

Patients treated with certain medications that inhibit blood clotting (anticoagulants of the warfarin type) may need to be readjusted because Arilin Rapid vaginal suppositories enhance the anticoagulant effect of these medications.

Caution is advised when administering medications with lithium (active ingredient given for certain forms of euphoric or depressed mood [manic-depressive states]), as an increase in lithium levels in the blood has been observed afterwards (risk of lithium poisoning with tremors and seizures).

The simultaneous administration of metronidazole with tacrolimus (agent to prevent rejection reactions in organ transplants) leads to an increase in tacrolimus blood levels. Therefore, have your tacrolimus blood levels and kidney function checked frequently.

The simultaneous use of metronidazole and amiodarone (agent for the treatment of heart rhythm disorders) can lead to an influence on heart activity. Therefore, heart activity should be regularly monitored by ECG. Consult your doctor as soon as you notice signs of a heart rhythm disorder such as dizziness, noticeable changes in heartbeat, or a brief fainting spell.

Other possible interactions

Metronidazole can lead to reduced values in some laboratory tests for determining a liver value (determination of GOT in serum).

When Arilin Rapid vaginal suppositories and latex products (e.g. condoms, diaphragms) are used simultaneously, the functionality and thus the safety of these products may be impaired for the duration of the use of Arilin Rapid vaginal suppositories.

Use of Arilin Rapid vaginal suppositories with food, drinks, and alcohol

The consumption of alcohol should be avoided, as otherwise intolerance reactions may occur, such as skin redness in the head and neck area, as well as nausea, vomiting, headaches, and dizziness.

Pregnancy and breastfeeding

The safety of using Arilin Rapid vaginal suppositories during pregnancy is not sufficiently proven. Therefore, Arilin Rapid vaginal suppositories should only be used during pregnancy, especially in the first trimester, if there is a compelling indication and if other therapeutic options are unsuccessful. Your doctor will decide on the application.

The active ingredient from Arilin Rapid vaginal suppositories passes into breast milk. Therefore, during therapy while breastfeeding, you should either interrupt breastfeeding or discontinue the medication and continue breastfeeding. In the case of a single dose during breastfeeding, breastfeeding should be suspended for 24 hours and the milk produced during this time should be pumped out.

Driving and using machines

Especially at the beginning of treatment, Arilin Rapid vaginal suppositories can impair your ability to react. You may no longer be able to react quickly and accurately enough to unexpected and sudden events. Do not drive a car or other vehicles! Do not operate electrical tools or machines! Do not work without a secure footing! Pay special attention that alcohol further worsens your ability to drive!

3. How to use Arilin Rapid vaginal suppositories?

Always use this medicine exactly as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

Dosage:

Unless otherwise prescribed by the doctor, the usual dose is:

For initial infections, a single application of an Arilin Rapid vaginal suppository is sufficient.

In severe cases and with recurrent infections, the 'two-day therapy' with 1 Arilin Rapid vaginal suppository each is preferable.

Method of administration

Arlin Rapid vaginal suppositories are vaginal suppositories for vaginal use (see illustration).

The vaginal suppositories are best inserted deeply into the vagina in the evening while lying on your back with slightly bent legs.

The treatment should not be carried out during menstruation.

Duration of use

The duration of treatment is generally 1–2 days.

Warning

As with other nitroimidazole-containing medicines, treatment with Arilin Rapid vaginal suppositories should generally not exceed 10 days. See also Chapter 2 'Special precautions for the use of Arilin Rapid vaginal suppositories are required'.

If you have used more Arilin Rapid vaginal suppositories than
You should

If a child has swallowed the vaginal suppositories, no severe symptoms of poisoning are expected. If symptoms occur, complete recovery is expected within a few days after medical treatment.

If you forget to use Arilin Rapid vaginal suppositories

Do not use a double amount if you have forgotten the previous application.

It may be necessary to extend the treatment by one day. Please speak to your doctor in such a case.

If you stop using Arilin Rapid vaginal suppositories

When you stop the treatment prematurely or interrupt it temporarily, you endanger the success of the treatment!

In case of unpleasant side effects, your doctor will discuss with you what countermeasures are available and whether other medications are suitable for you.

If you have further questions about the use of this medication, contact your doctor or pharmacist.

4. What side effects are possible?

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

The following categories are used for the frequency of side effects:

Very common: more than 1 in 10 treated

Common: 1 to 10 in 100 treated

Occasional: 1 to 10 in 1,000 treated

Rare: 1 to 10 in 10,000 treated

Very rare: less than 1 in 10,000 treated

Not known: Frequency cannot be estimated from the available data

When using Arilin Rapid vaginal suppositories, about 20% of the active ingredient enters the bloodstream. Side effects are rare in this case. Therefore, the following lists the same side effects that are possible with an oral metronidazole-containing medication.

Significant side effects or signs you should watch for and actions to take if you are affected:

If you are affected by any of the side effects listed below, do not continue using Arilin Rapid vaginal suppositories and consult your doctor as soon as possible.

Very rare side effects

- Anaphylactic shock (severe drop in blood pressure as a sign of hypersensitivity).

In severe, but very rare cases, shortness of breath, dizziness, and vomiting may occur. If there are disturbances of consciousness, cold sweats, and pale and cold hands and feet, a doctor must be called immediately. Until the doctor arrives, the patient's upper body should be kept flat and their legs elevated. To prevent cooling, the patient should be kept warm with a blanket. The usual appropriate emergency measures (e.g., antihistamines, corticosteroids, sympathomimetics, and possibly ventilation) must be initiated, and the treatment with Arilin Rapid vaginal suppositories must be stopped immediately.

- Reduction of blood platelets (thrombocytopenia).
- Lack of certain white blood cells (agranulocytosis). Agranulocytosis can develop within a few hours. Symptoms include fever,

Fatigue, inflammation of the tonsils and oral mucosa. In these cases, a blood count check must be carried out quickly. Contact the nearest available doctor immediately in such a case.

- Inflammation of the pancreas.

If severe, persistent diarrhea occurs during or in the first weeks after treatment, pseudomembranous enterocolitis (severe intestinal disease) should be considered (in most cases caused by *Clostridium difficile*). This antibiotic-induced intestinal disease can be life-threatening and requires immediate medical attention. The doctor must consider discontinuing therapy with Arilin Rapid vaginal suppositories depending on the indication and, if necessary, initiate appropriate treatment immediately (e.g., administration of specific antibiotics/chemotherapeutics whose effectiveness is clinically proven). Medications that inhibit bowel movement (peristalsis) must not be taken.

Occasional side effects

- Nerve disorders (peripheral neuropathies) and seizures. The former manifest as numbness, tingling, or prickling in the arms and legs. Even if these symptoms occur only mildly, you must contact your doctor immediately!

Not known

- Pathological changes in the brain, cerebellar syndrome (with, e.g., speech and gait disturbances, nystagmus, and muscle twitching), non-bacterial meningitis (aseptic meningitis)
- Severe skin reactions with life-threatening systemic reactions (e.g., erythema multiforme [inflammatory skin disease with redness], Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Hepatitis sometimes with jaundice
- In individual patients who were treated simultaneously with other antibiotics, cases of liver failure occurred that required a liver transplant.

Other possible side effects

Common side effects

- Metallic taste, bitter belching, tongue coating, inflammation in the mouth (glossitis, stomatitis), stomach pressure, nausea, vomiting, loss of appetite, diarrhea.
- Darkening of the urine (caused by a metabolic product, without clinical significance).

Occasional side effects

- Headaches, dizziness, drowsiness, insomnia, psychotic disorders including hallucinations and states of confusion, excitability, depressive mood, coordination disorders (ataxia).
- Skin reactions (e.g., itching, hives with blister and wheal formation [urticarial exanthem]), drug fever.
- Reduction of white blood cells (leukopenia and granulocytopenia). Therefore, regular blood count checks are necessary with prolonged use.
- Rapid onset hypersensitivity reactions (anaphylactic reactions). In mild cases, it can lead to inflammatory redness, wheal formation, allergic rhinitis, and allergic conjunctivitis of the eye.
- Painful urination (dysuria), bladder infection (cystitis), and involuntary leakage of urine (urinary incontinence).
- Liver function disorders.
- Yeast infections (e.g., Candida) in the genital area.
- Feeling of weakness (muscular), visual disturbances.

Very rare side effects

- (3-sn-Phosphatidyl)choline (from soybeans) can very rarely cause allergic reactions.
- Joint pain

Reporting side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly to the

Federal Institute for Drugs and Medical Devices

Dept. Pharmacovigilance

Kurt-Georg-Kiesinger-Allee 3

53175 Bonn

Website: www.bfarm.de. By reporting side effects, you can help provide more information about the safety of this medicine.

5. How to store Arilin Rapid Vaginal Suppositories?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the blister strip and the outer carton.

The expiry date refers to the last day of that month.

Do not store above 25 °C.

6. Contents of the pack and other information

What Arilin Rapid Vaginal Suppositories contain:

- The active substance is metronidazole. 1 vaginal suppository contains 1000 mg metronidazole.
- The other ingredients are: glycerol tri-alkanoate (C10-C18), (3-sn-phosphatidyl)choline (from soybeans).

What Arilin Rapid Vaginal Suppositories look like and contents of the pack

Arlin Rapid Vaginal Suppositories are whitish-yellowish vaginal suppositories in blister strips in the outer carton.

Arlin Rapid Vaginal Suppositories are available in packs of 2 vaginal suppositories for vaginal use.

Marketing authorization holder and manufacturer

Dr. August Wolff GmbH & Co. KG Arzneimittel

Sudbrackstraße 56

33611 Bielefeld

Phone: 0521 88 08-05

Fax: 0521 88 08-334

E-Mail: aw-info@drwolffgroup.com

This package leaflet was last revised in May 2018.