

PACKAGE LEAFLET

Package leaflet: Information for the user

Tranexaminezuur Midas 1000 mg, omhuld granulaat in sachet tranexamic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.
- If effect (decreased bleeding) has not occurred after the first day, stop treatment and discuss with your doctor.

What is in this leaflet

1. What Tranexaminezuur Midas is and what it is used for
2. What you need to know before you take Tranexaminezuur Midas
3. How to take Tranexaminezuur Midas
4. Possible side effects
5. How to store Tranexaminezuur Midas
6. Contents of the pack and other information

1. What Tranexaminezuur Midas is and what it is used for

Tranexaminezuur Midas is used for the reduction of heavy menstrual bleeding and should only be used when your periods are regular, 21 to 35 days with no more than 3 days individual variability in duration.

It contains tranexamic acid, which prevents the enzyme which dissolves blood clots to act. This causes less blood loss and quicker cure rate.

2. What you need to know before you take Tranexaminezuur Midas

Please note that Tranexaminezuur Midas should only be used if your periods are regular and heavy. To be sure, you should answer yes to both the following questions:

1. Are your periods regular, i.e. your menstrual cycle is between 21 to 35 days long (with no more than 3 days individual variability in duration)?
2. Do you need to use double sanitary protection, towels plus tampons or double towels to prevent bleeding through, alternatively change sanitary protection very often?

Do not take Tranexaminezuur Midas

- if you are treated for blood clot e.g in legs, lungs or brain
- if you have severe reduced kidney function
- if you have a history of convulsions (seizures or fits)
- if you are taking a combined hormonal contraceptive (“the pill”, vaginal ring or patch)
- if you are allergic to tranexamic acid or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Tranexaminezuur Midas if you have any of the followings:

- Your periods are irregular
- You have ever had a blood clot and your parents and/or brothers or sisters have had a blood clot
- You have had blood in your urine in between your periods
- You have reduced kidney function.

If heavy bleeding occurs during use of combined hormonal contraceptives (“the pill”, vaginal ring or patch), you should not start tranexamic acid, but consult your Healthcare Professional.

Heavy menstrual bleedings can occur due to diseases in the womb such as myoma or polyps. If they are taken care of, the heavy menstrual bleeding decreases. If anything is unclear, you should ask your doctor.

Continued gynaecological health controls are recommended.

If during treatment visual disturbances occurs such as visual impairment, vision blurred, impaired colour vision the treatment should be discontinued.

Children and adolescents

Ask your doctor before starting treatment if you are under 15 years old.

Other medicines and Tranexaminezuur Midas

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If Tranexaminezuur Midas is taken at the same time as anticoagulants, it could potentially affect the way that Tranexaminezuur Midas or the anticoagulants work.

Pregnancy and breast-feeding

Tranexaminezuur Midas is indicated for regular heavy menstrual bleedings and is not intended for use during pregnancy. Impact of breastfeeding for the child seems unlikely at therapeutic doses. Ask your doctor or pharmacist for advice if you are breastfeeding.

Driving and using machines

Side effects that can affect the ability to drive and use machines have been reported. If you feel dizzy or have problems with your eyesight you should not drive or use machines until the symptoms have passed.

Tranexaminezuur Midas contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Tranexaminezuur Midas

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your pharmacist if you are not sure.

Coated granules can be swallowed with a glass of water.

Treatment should start when your period has started. The recommended dose is 1 sachet 3 times daily as long as needed, for a maximum of 4 days. The dosage can be increased if the bleedings are very heavy. Do not use more than 4 sachets per day (1 sachet every 6 to 8 hours). Your doctor may prescribe a different dose.

If effect (decreased bleeding) has not occurred after the first day, stop treatment and discuss with your doctor.

If you take more Tranexaminezuur Midas than you should

If you have taken more Tranexaminezuur Midas than you should, or if children have been taking medicine by accident, contact your doctor or hospital to get an opinion of the risk and advice on action to be taken. Signs of an overdose may include dizziness, headache, nausea, diarrhoea, low blood pressure, myopathy and convulsions. It may include increased risk of thrombosis if you are predisposed.

If you forget to take Tranexaminezuur Midas

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Common (may affect up to 1 in 10 patients): Nausea, vomiting, diarrhoea, stomach pain, headache, dizziness. These side effects are often mild and transient.

Uncommon (may affect up to 1 in 100 patients): Allergic skin reactions.

Not known (frequency cannot be estimated from the available data): Rare cases of blood clots, changes in colour vision and other problems with the eyesight, convulsions, sudden onset kidney problems due to death of the tissue in the outer part of the kidney (acute renal cortical necrosis). An allergic reaction, that usually recurs at the same site(s) on re-exposure to the medication and may include round or oval patches of redness and swelling of the skin, blistering, and itching (fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur.

If Tranexaminezuur Midas does not have sufficient effect after the first day or if you do not tolerate Tranexaminezuur Midas, there are other methods to treat heavy menstrual bleedings. Contact your doctor who can give information about those methods.

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 listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tranexaminezuur Midas

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Tranexaminezuur Midas contains

- The active substance is tranexamic acid. Each sachet contains 1000 mg of tranexamic acid.
- The other ingredients are: Sugar spheres (sucrose, maize starch), Povidone K30 (E1201), Sucralose (E955), Silica colloidal anhydrous (E551), Polyacrylate dispersion 30 per cent, Talc (E553B).

What Tranexaminezuur Midas looks like and contents of the pack

Coated granules in sachet (LDPE / Aluminium / LDPE / Paper).

White to off-white coated granules.

Box of 12, 24, 36, 48 or 72 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Vergunninghouder:

MIDAS Pharma GmbH

Rheinstraße 49

West

55218 Ingelheim am Rhein

Duitsland

Fabrikant:

Athena IPS

Zone Industrielle N 2

1 Rue Nungesser

59121 Prouvy

Frankrijk

MIDAS Pharma GmbH

Rheinstraße 49

West

55218 Ingelheim am Rhein

Duitsland

In het register ingeschreven onder RVG 134772

This medicine is authorised in the Member States of the European Economic Area under the following names:

Deze bijsluiter is voor het laatst goedgekeurd in maart 2026.