HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use tranexamic acid USP tablets safely and effectively. See full prescribing information for tranexamic acid USP tablets.

TRANEXAMIC ACID USP TABLETS are indicated for the treatment of cyclic heavy menstrual bleeding (4).

CONTRAINDICATIONS
Hypersensitivity to tranexamic acid (4.2)

WARNINGS AND PRECAUTIONS
Venous and arterial thrombosis or thromboembolism, as well as cases of retinal artery and retinal vein occlusions, have been reported in patients using tranexamic acid. Patients should be instructed to report visual and ocular symptoms promptly. In the event of such symptoms, patients should be instructed to discontinue tranexamic acid USP Tablets and seek immediate medical attention (4.1). Cerebral edema and cerebral infarction may be caused by use of tranexamic acid USP tablets. In case of severe allergic reaction, discontinue tranexamic acid USP tablets and seek immediate medical attention (5.2). Ligneous conjunctivitis has been reported in patients taking tranexamic acid (5.4).

DOSAGE AND ADMINISTRATION
1. 1,300 mg (two 650 mg tablets) three times a day (3,900 mg/day) for a maximum of 5 days during monthly menstruation (2.1)
2. Renal impairment: Dosage adjustment is needed in severe (creatinine clearance [Cr] < 1.4 mg/dL) (2.2)
   - Cr 1.4 mg/dL or 2.8 mg/dL: 1,300 mg (two 650 mg tablets) two times a day (2,600 mg/day) for a maximum of 5 days during menstruation
   - Cr 2.8 mg/dL or above 5.7 mg/dL: 650 mg (one 650 mg tablet) once a day (650 mg/day) for a maximum of 5 days during menstruation

DOSAGE FORMS AND STRENGTHS
Tables: 650 mg (3)

CONTRAINDICATIONS
Women who are using combination hormonal contraception (4.1)
Women with known thromboembolic disease or a history or familial risk of thrombosis or thromboembolism, including retinal vein or artery occlusion (4.1)
Hypersensitivity to tranexamic acid (4.2)

WARNINGS AND PRECAUTIONS
Concomitant use of tranexamic acid USP Tablets with Factor V or protein C concentrates, or other procoagulant concentrates or all oral anticoagulant (and antiplatelet) may increase the risk of thrombosis. (5.1)
Visual or ocular adverse effects may occur with tranexamic acid USP Tablets. Immediately discontinue use if vision loss or ocular symptoms occur. (5.1)
If a case of severe allergic reaction, discontinue tranexamic acid USP Tablets and seek immediate medical attention. (5.2)
Ligneous conjunctivitis has been reported in patients taking tranexamic acid (5.4)

ADVERSE REACTIONS
Most common adverse reactions in clinical trials (≥5%) and more frequent in tranexamic acid USP tablets subjects compared to placebo subjects) are headache, rash or rashes, sinusitis, back pain, abdominal pain, musculoskeletal pain, joint pain, muscle cramps, rhinitis, and upper respiratory infection. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Amring Pharmaceuticals Inc. at 1-800-688-1088 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USP INTERACTIONS
Concurrent therapy with tissue plasminogen activators may decrease the efficacy of both tranexamic acid USP tablets and tissue plasminogen activators. (7.2)

USE IN SPECIFIC POPULATIONS
Geriatric Use (8.7)
Pediatric Use (8.9)
Nursing Mothers (8.10)
Pregnancy (8.11)

dose regimen

Table 1: Dosage of tranexamic acid USP tablets in Patients with Renal impairment

Transaxamic Acid USP Tablets

<table>
<thead>
<tr>
<th>Serum Creatinine (mg/dL)</th>
<th>Adjusted Dose</th>
<th>Total Daily Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cr above 1.4 and ≤ 2.8</td>
<td>1,300 mg (two 650 mg tablets) two times a day</td>
<td>2,600 mg</td>
</tr>
<tr>
<td>Cr above 2.8 and ≤ 5.7</td>
<td>1,300 mg (two 650 mg tablets) once a day</td>
<td>1,300 mg</td>
</tr>
<tr>
<td>Cr above 5.7</td>
<td>650 mg (one 650 mg tablet) once a day</td>
<td>650 mg</td>
</tr>
</tbody>
</table>

3. DOSAGE FORMS AND STRENGTHS
650 mg tablets

4. CONTRAINDICATIONS
6.1. Thrombolytic Risk

3. WARNINGS AND PRECAUTIONS
5.1. Thrombolytic Risk

Concomitant use of tranexamic acid USP tablets with Factor V or protein C concentrates, or other procoagulant concentrates or all oral anticoagulant (and antiplatelet) may increase the risk of thrombosis. (5.1)

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DOSAGE AND ADMINISTRATION
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DOSAGE FORMS AND STRENGTHS
Tablets: 650 mg (3)

CONTRAINDICATIONS
Women who are using combination hormonal contraception (4.1)
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Most common adverse reactions in clinical trials (≥5%) and more frequent in tranexamic acid USP tablets subjects compared to placebo subjects) are headache, rash or rashes, sinusitis, back pain, abdominal pain, musculoskeletal pain, joint pain, muscle cramps, rhinitis, and upper respiratory infection. (6.1)

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USP INTERACTIONS
Concurrent therapy with tissue plasminogen activators may decrease the efficacy of both tranexamic acid USP tablets and tissue plasminogen activators. (7.2)

USE IN SPECIFIC POPULATIONS
Geriatric Use (8.7)
Pediatric Use (8.9)
Nursing Mothers (8.10)
Pregnancy (8.11)
5.3 Salbutamol/Intal

Clinical use and early diagnosis in infants may be caused by use of tranexamic acid USP tablets in women with subclinical hemorrhage.

5.4 Lignocaine

Serum lignocaine concentrations have been reported in patients taking tranexamic acid. The concentrations followed no evidence of cessation of the drug.

5.5 ADVERSE REACTIONS

4.2 Pharmacokinetics

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the trials of a drug cannot be directly compared to the rates observed in another trial and may not reflect the rates observed in clinical practice.

5.6 Clinical Experience

The safety of tranexamic acid USP tablets in the treatment of heavy menstrual bleeding (HMB) was studied in two randomized, double-blind, placebo-controlled studies (see Clinical Studies (14)). One study compared the effects of two doses of tranexamic acid USP tablets, 1500 mg and 3900 mg given daily for up to 5 days during each menstrual period versus placebo over a 3-cycle treatment duration. A total of 264 women were randomized to this study, with 111 receiving at least one dose of 3900 mg of tranexamic acid USP tablets. A secondary objective compared the effects of tranexamic acid USP tablets (3900 mg/d) versus placebo over a 6-cycle treatment duration. A total of 186 women were randomized to this study, with 117 receiving at least one dose of tranexamic acid USP tablets.

All adverse events and all treatment-emergent adverse events occurring in 1% or more of patients in the two studies are listed below. These are based on spontaneous reports submitted by investigators as adverse event data from clinical trials are often not subject to any formal data collection and are subject to reporting bias. These events are double entered and their rates are not adjusted for differences in study design or duration. In addition, the following adverse reactions have been identified from postmarketing experience with tranexamic acid USP tablets:

• Arthralgia includes joint stiffness and swelling
• Includes headache and tension headache
• Includes headache and tension headache
• ANEMIA
• BACK PAIN
• NASAL & SINUS SYMPTOMS

The following adverse reactions have been identified from postmarketing experience with tranexamic acid USP tablets:

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• BACK PAIN
• NASAL & SINUS SYMPTOMS

According to the Canada Centre for Drugs and Therapeutics, the prevalence of use of tranexamic acid tablets in Canada is not known. A limited number of cases of intentional overdose with tranexamic acid USP tablets are known. No specific information is available on the treatment of overdose tranexamic acid tablets. In general, the following interventions may be useful:

• Immediate gastric lavage
• Removal of unabsorbed drug by decontamination of the gastrointestinal tract
• Hemodialysis

In the event of severe bleeding or delayed bleeding after surgery, intravenous tranexamic acid may be considered. In cases of severe or life-threatening bleeding, the dosage may be increased up to 300 mg IV every 4 hours. In cases of delayed bleeding, the dosage may be increased up to 90 mg IV every 6 hours. The dosage may be decreased up to 30 mg IV every 6 hours in cases of mild or moderate bleeding. The dosage may be increased up to 150 mg IV every 6 hours in cases of severe bleeding.

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After a single and administration of tranexamic acid, the peak plasma concentration (C_max) occurred at approximately 3 hours (T_max). The absolute bioavailability of tranexamic acid USP tablets in women aged 18-49 is approximately 4%. Following multiple administration of tranexamic acid USP tablets, laboratory parameters including hematology, clinical chemistry, urinalysis and renal function were evaluated. The concentration is 40 mg/kg/day. The mean area under the plasma concentration time curve (AUC) remained unchanged, compared to a single oral dose (two 650 mg tablets). Plasma concentrations reached steady state at the 5th dose of tranexamic acid USP tablets on Day 24. The terminal elimination half-life (t1/2) of the parent compound was determined in 10 healthy women following a single (two 650 mg tablets) and multiple (two 650 mg tablets) three daily for 5 days dose of tranexamic acid USP tablets are shown in Table 3.

In these studies, the primary outcome measure was menstrual blood loss (MBL), measured using the alkaline hematin method. The were Black, and 5% were Asian, Native American, Pacific Islander. In a 9-year prospective study, Black women were 2.4 times more likely to experience a reduction in MBL compared to White women (p = 0.002). The efficacy and safety of tranexamic acid USP tablets in the treatment of heavy menstrual bleeding was evaluated. One percent of 0.5 mg once daily of tranexamic acid 3900 mg/day showed an increase in incidence of infections which may have been related to treatment. Female mice were included in the experiments. Oropharyngeal Conway and antiplasminogen activator activity were determined. Therefore, exercise caution if a patient taking tranexamic acid USP tablets therapy requires tissue plasminogen activator USP tablets. Tranexamic Acid USP Tablets are indicated for women of reproductive age and are not intended for use by postmenopausal women.

Specific Populations

Pediatric Use

Distribution

Table 5: Secondary Outcomes in 3 cycle Treatment of tranexamic acid USP tablets and Multiple Cycle 650 mg tablets three days for 5 days Administration of tranexamic acid USP tablets in 15 Healthy Women under Feeding Conditions

- Chromatography

No drug treatment data available. Concomitant therapy with tissue plasminogen activator, Factor IX Complex Concentrates or Anti-oxytocin USP tablets is CONTRAINDICATED. Therefore, concomitant therapy with tissue plasminogen activator, Factor IX Complex Concentrates or Anti-oxytocin USP tablets is CONTRAINDICATED. Therefore, concomitant therapy with tissue plasminogen activator, Factor IX Complex Concentrates or Anti-oxytocin USP tablets is CONTRAINDICATED. Therefore, concomitant therapy with tissue plasminogen activator, Factor IX Complex Concentrates or Anti-oxytocin USP tablets is CONTRAINDICATED. Therefore, concomitant therapy with tissue plasminogen activator, Factor IX Complex Concentrates or Anti-oxytocin USP tablets is CONTRAINDICATED.
How should I take tranexamic acid USP tablets?

Transaminic Acid USP Tablets may be taken with or without food. Once your period has started, take 2 tablets of tranexamic acid USP tablets three times per day (e.g., in the morning, aftern...

What is tranexamic acid USP tablets?
TRANEXAMIC ACID, USP TABLETS

Limitations on social, leisure, and physical activities were also statistically significantly reduced in the tranexamic acid 3900 mg/day tranexamic acid USP tablets group compared to placebo (see Table 7). No statistically significant treatment difference was observed in response rates on the number of large stains.

Reduction in Large Stains

Positive means reflect an improvement from baseline.

Least Squares Mean Reduction

Least Squares Mean (95% CI)

Table 7: Secondary Outcome in 6 Cycle Study

How do I know if I have a blood clot?

Inform patients that they should stop tranexamic acid USP tablets and seek immediate medical attention if they notice symptoms of a severe allergic reaction (e.g., swelling of face, mouth, throat or airway). Inform patients that common side effects of tranexamic acid USP Tablets include headache, visual and nasal symptoms, back pain, abdominal pain, nausea, vomiting, diarrhea, and fatigue.

Avoid patients to contact their healthcare provider if they have heavy menstrual bleeding symptoms persist or worsen.

Pregnancy Information

TRANEXAMIC ACID, USP TABLETS

What is tranexamic acid USP tablets used to treat?

Transaminic Acid USP Tablets are a prescription medicine used to treat your heavy menstrual period (menstruation) when your bleeding gets in the way of social, leisure and physical activities. Tranaminic Acid USP Tablets do not contain any hormones. On average, tranaminic Acid USP Tablets help reduce the amount of blood lost during your monthly period. They are not a form of birth control that can prevent pregnancy.

Transaminic Acid USP Tablets are taken once during your period and do not interact with your monthly menstrual symptoms (soreness, bloating, and cramps) or your period cycle.

Transaminic Acid USP Tablets do not affect your fertility and cannot be used to prevent pregnancy. Transaminic Acid USP Tablets have not been studied in adolescents younger than 18 years of age.

Transaminic Acid USP Tablets are not for women who have already gone through menopause (postmenopausal).

Who should not take tranexamic acid USP tablets?

Do not take tranexamic acid USP tablets if you:
- Are using a form of birth control that contains estrogen and a progestin (like a birth control pill, patch, or vaginal ring). Ask your healthcare provider before taking tranexamic acid USP Tablets if you are not sure if your birth control method contains estrogen and a progestin.
- Currently have a blood clot
- Have ever had a blood clot
- Are allergic to tranexamic acid

When should I not take tranexamic acid USP Tablets?

Before taking tranexamic acid USP Tablets, talk to your healthcare provider about all of your medical conditions, including:

- Other medicines or supplements you take, including prescription and over the counter medicines, vitamins, and herbal supplements

Ask your healthcare provider if you are not sure if your medicine is one that is described above.

What are the possible side effects of tranexamic acid USP tablets?

Transaminic Acid USP Tablets can cause serious side effects, including:

What are the possible side effects of tranexamic acid USP tablets?
Blood clots. You may have a higher risk of having serious blood clots if you take tranexamic acid USP tablets with:
- medicines used to help your blood form clots
- some medicines used to treat leukemia
- Eye changes. Stop taking tranexamic acid USP tablets and promptly report any eye problems you have while taking tranexamic acid USP tablets. Your doctor will refer you to an eye doctor who will examine your eyes.

The most common side effects of tranexamic acid USP tablets include:
- Headache
- Sinus and nasal problems
- Back pain
- Pain in your abdomen
- Pain in your muscles or joints
- Anemia
- Fatigue

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of tranexamic acid USP tablets. For more information, ask your healthcare provider or pharmacist.

If you notice a change in your usual bleeding pattern that worries you, or your heavy bleeding continues, contact your healthcare provider right away. This may be a sign of a more serious condition.

Tell your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. You may also report side effects to Amring Pharmaceuticals Inc. at 1-844-Amring1 (1-844-267-4641).

How should I store tranexamic acid USP tablets?
- Store tranexamic acid USP tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep tranexamic acid USP tablets and all medicines out of the reach of children.

General information about tranexamic acid USP tablets
- Medicines are sometimes prescribed for medical conditions that are not mentioned in Patient Information Leaflets. Do not use tranexamic acid USP tablets for a condition for which it was not prescribed. Do not give tranexamic acid USP tablets to other people, even if they have the same symptoms that you have, it may harm them.
- This Patient Information leaflet summarizes the most important information about tranexamic acid USP tablets. If you would like more information about tranexamic acid USP tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about tranexamic acid USP tablets that is written for healthcare professionals. For more information, call 1-844-Amring1 (1-844-267-4641).
- What are the ingredients of tranexamic acid USP tablets?
- Active ingredient: tranexamic acid
- Inactive ingredients: microcrystalline cellulose, colloidal silicon dioxide, pregelatinized corn starch, povidone, hypromellose, stearic acid, and magnesium stearate.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Manufactured for:
Amring Pharmaceuticals Inc.
Bergen, PA 19312

Manufactured by:
Mikart, LLC.
Atlanta, GA 30318

Rev. 03/2019
1221E00