

PACKAGE LEAFLET INFORMATION



ARINNA 40 mg Enteric Coated Tablet
For oral use

Active Ingredient: Each enteric coated tablet contains 45.10 mg pantoprazole sodium sesquihydrate equivalent to 40 mg of pantoprazole.

Inactive Ingredients: Sodium carbonate anhydrous, mannitol, povidone (K-90), povidone (K-25), crospovidone, talc, calcium stearate, hydroxy propyl methyl cellulose (E5), polyethylene glycol (400), triethyl citrate, eudragit-L30D, titanium dioxide and yellow iron oxide.

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, please ask to your doctor or pharmacist.*
- *This medicine has been prescribed only for you. Do not pass it on to others.*
- *If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.*
- *Please strictly follow instructions in this prescribing leaflet. Do not take **lower or higher** dose than recommended dose.*

What is in this leaflet:

1. What ARINNA is and what it is used for?
2. What you need to know before you take ARINNA.
3. How to take ARINNA?
4. What are possible side effects?
5. How to store ARINNA?

1. What is ARINNA and what it is used for?
 - ARINNA, presented to take in the way coated tablets with special substance (enteric coated) that prevents the dissolution in the stomach Each tablet contains 45.10 mg pantoprazole sodium sesquihydrate equivalent to 40 mg pantoprazole as the active ingredient.
 - ARINNA contains the active substance pantoprazole. Pantoprazole is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.
 - ARINNA is presented to the market in 14 and 28 tablets Al / Al blister packages. The tablets are oval, biconvex shaped, yellow in color.

ARINNA;

Children and adolescents 12 years of age above for:

- Gastro-esophageal reflux disease (GERD: content stomach back away from to esophagus

Adults:

- An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (eradication therapy). The aim is to get rid of the bacteria and so reduce the likelihood of these ulcers returning.
- Stomach and duodenal ulcers.
- Zollinger-Ellison-Syndrome and other conditions producing too much acid in the stomach.

**2. What you need to know before you take ARINNA
DO NOT TAKE ARINNA:**

- If you are allergic (hypersensitivity) to pantoprazole or to any of the other ingredients of ARINNA, the benzimidazoles (drugs used for fungal diseases), do not use ARINNA
- If you are allergic to medicines containing other proton pump inhibitors, do not use ARINNA.

TAKE SPECIAL CARE with ARINNA in the following situations

- If you have severe liver problems and had problems with your liver in the past, please tell your doctor. The doctor will check your liver enzymes more frequently, especially when you are taking ARINNA as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you are on ARINNA, for more than three months, it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor immediately. Low magnesium levels may also lead to a reduction in potassium or calcium levels in your blood.

Your doctor may decide to perform regular blood tests to monitor your magnesium levels.

- Alcohol consumption during treatment is to be avoided.
- If you have had a skin reaction after treatment with a drug similar to ARINNA, which reduces stomach acidity,
- Tell your doctor as soon as possible if you have a rash at your skin, particularly in sun-exposed areas, because you may need to stop your treatment with ARINNA. If you have other discomforts such as pain in your joints, do not forget to mention them.
- If you take neuroendocrine tumors tests, please tell your doctor. Because ARINNA affects treatment outcome as all proton inhibitors.
- Such as all proton inhibitors, ARINNA may increase the number of bacteria that are normally present in the upper gastrointestinal tract and thus the risk of infection (Salmonella, Campylobacter and C diffile) to be minimal.
- Non-steroidal anti-inflammatory drugs (non-steroidal anti-inflammatory drugs) are used to prevent ulcers triggered by NSAIDs, use of ARINNA may be necessary for patients who need continuous NSAID drug use, have a high risk of developing adverse events in the gastrointestinal tract (e.g., over the age of 65, ulcer or history of stomach bleeding) should be limited to patients.
- If you are going to do a specific blood test (Chromogranin A)

If you notice any of the following, contact your doctor **IMMEDIATELY:**

- An unintentional loss of weight
- Vomiting, especially if repeated
- Vomiting blood; this may appear as dark coffee grounds in your vomit
- You notice blood in your stools; which may be black or tarry in appearance
- Difficulty in swallowing or pain when swallowing
- Looking pale and feel weak (anaemia)
- Chest pain
- Stomache ache

If any of the above applies to you, even for any period at past, please contact your doctor.

Treatment with ARINNA may suppress the cancer-related symptoms and ultimately delay diagnosis. For this reason, before your ARINNA treatment, your doctor can do some tests to make sure you are not a cancer patient. If symptoms persist during your treatment, other studies may be needed.

If you are using ARINNA for 1 year longer, your doctor will probably keep you under regular observation. If you see new and unusual symptoms, you should definitely tell them when you go to your doctor.

Taking ARINNA with food and drink:

Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Pregnancy

Consult your doctor or pharmacist before using this medicine.

There are no adequate data from the use of pantoprazole in pregnant women. If you think you are pregnant or pregnant, but your doctor thinks that the benefit of the medicine for you is more than the risk of harming your unborn baby, you should use pantoprazole.

If you notice that you are pregnant during your treatment, immediately contact your doctor or pharmacist.

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

Excretion into human milk has been reported. Breastfeeding mothers should use this medicine, only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Driving and using machines

ARINNA has no or negligible effect on the ability to drive and use machinery.

If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Important information about some of the inactive ingredients of ARINNA

The warning does not contain the necessary inactive ingredients.

Taking other medicines

ARINNA may disrupt the effectiveness of other medicines, so tell your doctor if you take the following medicines;





- Pantoprazole may weaken its efficacy by reducing the absorption of drugs intended to prevent fungal infections, such as ketoconazole, itraconazole and posaconazole, or certain cancer drugs, such as erlotinib, whose absorption is dependent on the acid level (pH).
- You may need more control if you are using warfarin and phenprocumone, which affects blood thinning or thinning.
- Drugs used in the treatment of HIV (AIDS) such as

60 mm

60 mm

60 mm

60 mm

ÜRÜN ADI	ARİNNA KT		ORJİNAL 	NUMUNE 	ÇALIŞMA NO.	1
DEĞİŞİKLİK TARİHİ	9 Mart 2020		EBAT	155 x 350mm	BİÇAK NO.	
HAZIRLAYAN	RENKLER		MALZEME CİNSİ	1. Hamur 60 g	AÇIKLAMA 8 punto ile çalışıldı.	
Nazife Uygur  <small>Ankara Savaşçı ve Ticaret A.Ş.</small>		Black 	FARMA KOD	6343		
			KONTROL NO	A20015825/00		

Atazanavir,
• Methotrexate (used in the treatment of rheumatoid arthritis, psoriasis and cancer) - if you are taking methotrexate, your doctor may temporarily stop ARINNA treatment because pantoprazole may increase the level of methotrexate in the blood,
• Fluvoxamine (used in the treatment of depression and other psychiatric disorders) - if you are using, your doctor can reduce the dose of pantoprazole,
• Rifampicin (used in the treatment of infections),
• St. John’s wort (Hypericum perforatum) (used in the treatment of mild depression).

If you are currently taking or have recently taken any prescription or non-prescription medicine, please give information to your doctor or pharmacist accordingly.

3. How to take ARINNA?
Administration way and method:

Take the tablets 1 hour before a meal without chewing or breaking them and swallow them whole with some water.

Adults and adolescents 12 years of age and above
In the treatment of reflux esophagitis (escape of food and acid from the stomach) and related symptoms (eg, burning and pain in the torso, retraction of the stomach acid to the eating habit, pain during swallowing)

The usual dose is one tablet a day. Your doctor may tell you to increase to 2 tablets daily. The treatment period for reflux oesophagitis is usually between 4 and 8 weeks. Your doctor will tell you how long to take your medicine.

Adults
For the treatment of an infection with a bacterium called Helicobacter pylori in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).

One tablet, two times a day plus two antibiotic tablets of either amoxicillin, clarithromycin and metronidazole (or tinidazole), each to be taken two times a day with ARINNA tablet. Take the first ARINNA tablet 1 hour before breakfast and the second ARINNA tablet 1 hour before your evening meal. Follow your doctor's instructions and make sure you read the package leaflets for these antibiotics. The usual treatment period is one to two weeks.

For the treatment of stomach and duodenal ulcers.
The recommended dose is ARINNA, 1 tablet per day. Your doctor may recommend using 2 tablets ARINNA per day. The duration of treatment for gastric ulcer is usually 4-8 weeks. For duodenal ulcer, the duration of treatment is usually 2-4 weeks. With ARINNA your doctor will tell you how long your treatment will last.

For the long-term treatment of Zollinger-Ellison-Syndrome and of other conditions in which too much stomach acid is produced.
The recommended starting dose is usually two tablets a day. Take the two tablets 1 hour before a meal. Your doctor may later adjust the dose, depending on the amount of stomach acid you produce. If prescribed more than two tablets a day, the tablets should be taken twice daily. If your doctor prescribes a daily dose of more than four tablets a day, you will be told exactly when to stop taking the medicine.

Different age groups:

Use in children:
These tablets are not recommended for use in children below 12 years.

Use in the elderly:
ARINNA can be used for elderly patients without dose adjustment.

Special Uses
Kidney failure:
If you have renal dysfunction, do not use ARINNA for Helicobacter pylori treatment.

Liver failure:
If you have severe or moderate liver problems, do not use ARINNA for Helicobacter pylori treatment. Patients with severe hepatic impairment should not exceed 20 mg pantoprazole daily.

If you have an impression that the effect of ARINNA is too strong or too weak, talk to your doctor or pharmacist.

If you take more ARINNA than you should
There is no known indication of overdose.
If you use ARINNA more than necessary, talk to a doctor or pharmacist.

If you forget to take ARINNA
If you forget to take your medicine, do not take double doses to compensate for the forgotten desire. Your treatment will not continue from the next dose, according to the dose schedule given by your doctor.

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

Possible effects after completion of ARINNA treatment
Your doctor will tell you how long to take ARINNA. Do not give treatment early, because the symptoms of your disease may return or become severe.

4. What are the possible side effects?
Like all medicines, ARINNA can cause side effects on people, who have sensitivity to any of other ingredients of this medicine.

Side effects are classified according to the following frequency ratings:

Very common (may affect up to 1 in 10 patients)
Common (may affect up to 1 in 100 patients)
Uncommon (may affect up to 1 in 1000 patients)
Rare (may affect up to 1 in 10,000 patients)
Very rare (less than 1 in 10,000 patients)
Unknown (frequency cannot be estimated from the available data)

If you get any of the following side effects, stop taking ARINNA and tell your doctor IMMEDIATELY, or contact the emergency service at your nearest hospital:
• **Very serious allergic disorders (frequency rare):**
Swelling of the tongue and / or throat, difficulty in swallowing, hives (urticaria), difficulty in breathing, allergic swelling (Quincke's oedema/ angioedema), dizziness with very very fast heartbeat and sweating.
• **Serious skin conditions (frequency not known):**
Blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth / lips and genitals (these are Steven Johnson Syndrome, Lyell Syndrome and Eritema multiforme) and sensitivity to light.
• **Other serious conditions (frequency not known):**
Yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys).

All these are serious side effects.

If one of these side effects exists in you, it means that you have a serious allergy to ARINNA. You may need to get an emergency medical intervention or to be hospitalized.

Tell your doctor if you notice any of the following symptoms:
• **Common** (may affect up to 1 in 100 people)
Benign polyps in the stomach.
• **Uncommon** (may affect up to 1 in 1000 people)
Headache; dizziness; diarrhea; not feeling well; vomiting; tongue swelling and gas; constipation; dry mouth; abdominal pain; allergic disorders such as rash, itching and skin rash; fatigue, sleep disorders, hip, wrist or spine fracture,
• **Rare** (may affect up to 1 in 10,000 people)
Distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; high fever; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males (gynecomasty).
• **Very Rare** (less than 1 in 10,000 patients)
Disorientation.
• **Not known** (frequency cannot be estimated from the available data)
Especially in patients who are prone to seeing or hearing (hallucination) things that do not really exist, loss of time and space harmony and confusion of mind; decrease in blood sodium level (hyponatremia) decrease in blood magnesium level (see "2. Things to consider before using ARINNA"), rash, possibly with pain in the joints.

Side effects identified through blood tests:
• **Uncommon** (may affect up to 1 in 1000 patients):
An increase in liver enzymes
• **Rare** (may affect up to 1 in 10,000 patients):
An increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.
• **Very rare** (less than 1 in 10,000 patients):
Decrease in the number of blood cells (platelets) that lead to coagulation (this may cause more bleeding than normal); a decrease in the number of white blood cells (white blood cells) (which may lead to more frequent infection); (red blood cell), white blood cell (white blood cell), and blood cell (platelet) that provides clotting may all be at the same time abruptly reduced.

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting of Side Effects
If you get any side effects listed or not listed in this leaflet, please give information to your doctor, pharmacist or nurse. You can also report side effects directly to Turkish Pharmacovigilance Center (TÜFAM) by calling 0 800 314 00 08 or by clicking “Medicine Side Effect Notice” icon at www.titck.gov.tr. By reporting the occurred side effects, you can help provide more information on the safety of this medicine.

5. How to store ARINNA?
Keep ARINNA out of sight and reach of children, and store in its package.
Keep this medicine at room temperature lower than 25°C.
Use in accordance with the expiration date.
Do not use ARINNA after the expiry date, which is stated on the package.
If you notice any defects in the product and/or package, do not use ARINNA.

Registration Holder: Terra İlaç ve Kimya San. Tic. A.Ş.
İnkılap Mah. Küçüksu Cad. No:109 / C Blok
Kat:5 D:20-21 Ümraniye - İstanbul
Tel:(216) 523 77 77

Manufacturer: Abdi İbrahim İlaç San. ve Tic. A.Ş.
Orhan Gazi Mahallesi, Tunç Caddesi No:
3 Esenyurt – İstanbul
Tel:(212) 622 66 00 Fax:(212) 623 19 52

This leaflet is approved on 31/03/2018.