



PACKAGE LEAFLET: INFORMATION FOR THE USER

APRALJIN FORTE 550 mg Film Coated Tablet Taken by mouth

Active substance: Each tablet contains 550 mg naproxen sodium.

Excipients: Microcrystalline cellulose PH 101, Microcrystalline cellulose PH 102, starch, pregelatinized starch 1500, polyvinyl pyrrolidone K25, magnesium stearate.

Film coating agents: (Opadry OY-D-7233 white) Hypromellose, titanium dioxide, talk, polyethylene glycol, sodium lauryl sulfate.

Read all of this PACKAGE 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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

- 1. What APRALJIN FORTE is and what it is used for**
- 2. What you need to know before you take APRALJIN FORTE**
- 3. How to take APRALJIN FORTE**
- 4. Possible side effects**
- 5. How to store APRALJIN FORTE**

1. WHAT APRALJIN FORTE IS AND WHAT IT IS USED FOR

- APRALJIN FORTE is presented as white coated oblong tablets scored on side, in blister packages of 10 and 20 tablets.
- APRALJIN FORTE belongs to a medicine group effective against pain and inflammation called NSAIDs and has pain reducing effect.

APRALJIN FORTE tablets are used to treat:

- Inflammation of the joints (arthritis) characterized with pain and function loss, degeneration of the joint cartilage caused by trauma or other conditions,
- Painful inflammation of the hand and feet joints,
- Ankylosing spondylitis, a condition similar to rheumatoid arthritis occurring especially on the spine,
- Against inflammation and pain in rheumatoid diseases such as severe pain of the connective tissue and joint cartilage due to a disorder of the breakdown of proteins (acute gout),
- In acute musculoskeletal system (bone) pain,
- For pain relief against menstrual cramps in women,
- For pain relief in orthopedic and other surgeries.



2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE APRALJIN FORTE

DO NOT TAKE APRALJIN FORTE

Risks on the cardiovascular system

- NSAIDs may cause an increased risk of serious cardiovascular thrombotic events (related to blood clotting), myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

APRALJIN FORTE is contraindicated for the treatment of peri-operative pain in coronary artery “bypass” surgery.

Risks on the gastrointestinal system

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and with or without any previous warning symptoms. Elderly patients are at greater risk for these serious effects.

Do not take, if:

- You are allergic (hypersensitive) to the ingredients of APRALJIN FORTE, naproxen or medicines containing naproxen sodium or if you had skin rash, hives, asthma syndrome, inflammation of the nasal and nasal cavities while taking acetylsalicylic acid or other medicines against pain, fever and inflammation.
- You had previously bleeding or damage in your stomach and intestines while taking medicines against pain, fever and inflammation or if you have an active or recurring stomach or duodenal ulcer or if you had two or more distinct episodes of proven ulceration or bleeding.
- Severe kidney, liver or heart failure.
- Before or after coronary artery bypass surgery.
- You are breastfeeding or are in the last trimester of pregnancy.

TAKE SPECIAL CARE with APRALJIN FORTE,

- Avoid taking with any in the group of medicines against pain, fever and inflammation.
- You can reduce the side effects to a minimum by taking the lowest effective dose for the shortest period necessary for treatment.
- If you have a previous history of severe stomach and intestinal disease or symptoms thereof, you may develop anytime during treatment bleeding, ulceration and damage, which can be severe. Depending on the bleeding, you may experience symptoms like dark colored feces, blood in the mouth and indigestion. Severe gastrointestinal disorders due to medicines against pain, fever and inflammation, have occurred mostly in elderly or disabled patients. Therefore, if you have severe gastrointestinal diseases like ulcers, bleeding or damage, your doctor will advise you to start with the lowest dose and take with some protective medicines (misoprostol or proton pump inhibitors). If you are taking low dose acetylsalicylic acid or other medicines which may cause gastrointestinal bleeding, you may need to take a protective medicine.
- If you have an inflammatory bowel disease (ulcerative colitis, Crohn disease), you should be careful while taking medicines against pain, fever and inflammation, as they may increase the severity of your discomfort. If you had previous gastrointestinal intoxication, inform your doctor in case of any symptom of stomach disorder (diarrhea, vomiting, weight loss). Do not continue your treatment with APRALJIN FORTE in case of gastrointestinal bleeding or ulceration.
- If you have any gastrointestinal disease, use APRALJIN FORTE under supervision of your



doctor.

- Severity and frequency of the gastrointestinal disorders may increase with the increase in the dosage and treatment period of APRALJIN FORTE, as it is with other medicines against pain, fever and inflammation.
- Be careful when you are taking together with oral contraceptives, medicines that prevent blood clotting such as warfarin, medicines like acetylsalicylic acid, which increase the risk of bleeding and ulceration.
- Elderly patients should take the lowest dose of APRALJIN FORTE, against the possibility of increased frequency of severe gastrointestinal bleeding and damage.
- Do not use APRALJIN FORTE further, when your skin is peeling, when your mucosa is damaged or any hypersensitivity reaction occurs on your skin and go to a doctor as soon as possible.
- Use with care in case of hypersensitivity reactions like swelling of your face and throat due to allergies, tightening of your bronchi (asthma) or running nose. In patients with asthma or allergic diseases or sensitivity to acetylsalicylic acid, spasm formation in the bronchi may be accelerated
- As with other medicines against pain, fever and inflammation, APRALJIN FORTE should be used with care in patients with kidney diseases. Be careful if you have any disease causing the blood volume or the blood flow in the kidneys to decrease, you have heart failure or any impairment in your liver functions. Your doctor may decrease your APRALJIN FORTE dosage.
- As with other medicines against pain, fever and inflammation, APRALJIN FORTE may increase some values in your liver function tests. Symptoms or signs indicating liver function impairment (nausea, fatigue, dizziness, rash, jaundice, pain in the right upper abdomen, cold-like symptoms) should be carefully monitored. Caution should be exercised against severe liver disorders including jaundice and hepatitis.
- Naproxen sodium causes increase in blood clotting time by reducing the aggregation of platelets. Therefore if you have any blood clotting disease, continue your treatment with APRALJIN FORTE under supervision of your doctor. While taking APRALJIN FORTE, you may have an increased risk of bleeding, if you under a high risk of bleeding or if you are taking any medicines preventing blood clotting.
- If visual disorders occur in patients during treatment with APRALJIN FORTE, ophthalmologic examination should be carried out.
- Be careful while taking APRALJIN FORTE if you have a high blood pressure or heart failure, as medicines against fever and inflammation may cause risk of fluid retention and edema.
- Inform your doctor if you have an uncontrollable high blood pressure, shortness of breath due to heart failure, edema, a distinct disease characterized with liver growth or insufficient blood flow to the heart. Your doctor will take these disorders into consideration during your treatment with APRALJIN FORTE.
- In case of high cardiovascular disease risk (high blood pressure, diabetes, smoking), your doctor will take these disorders into consideration during your treatment with APRALJIN FORTE.
- As with other medicines against pain, fever and inflammation, APRALJIN FORTE may cause severe side effects like heart attack or stroke, which can be fatal or may require hospitalization. Although these severe cardiovascular incidents may occur without any warning symptoms, go to a doctor if you experience any signs and symptoms like chest pain, shortness of breath, fatigue, difficulty speaking.
- Caution is advised when used in patients in risk of Alzheimer's disease (a disease characterized with forgetfulness.)

If these warnings are valid for you, even for a period of time in the past, please consult to your doctor.



Taking APRALJIN FORTE with food and drinks

Use APRALJIN FORTE after meals.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Risk and benefits to the patients should be very well evaluated. Therefore this medicine should not be used during pregnancy unless clearly necessary.

If you notice that you are pregnant during the treatment consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

It should not be prescribed to nursing mothers as naproxen sodium is excreted in breast milk.

Driving and using machines

Taking APRALJIN FORTE may cause dizziness, drowsiness or insomnia or depression in some patients. Therefore if you experience any of these side effects, be careful when performing activities that require attention.

Important information about some of the ingredients of APRALJIN FORTE

APRALJIN FORTE does not contain any excipient requiring any warning.

Using with other medicines

It is not advised to take APRALJIN FORTE with other medicines effective against pain, fever and inflammation.

The effect of APRALJIN FORTE may be delayed when taken in combination with medicines regulation stomach acid or colestyramine.

Naproxen sodium is bound to proteins called albumin in the blood. As it may interact with other medicines binding to albumin like coumarin-type medication preventing clotting, sulfonylureas, hydantoin, other pain, fever and inflammatory medicines (NSAID), and acetylsalicylic acid, your doctor may adjust your dosage. Naproxen sodium may prolong blood clotting by reducing the activity of cells called platelets, which are involved in blood clotting by aggregation.

It may diminish the effects of diuretics like furosemide when used in combination.

When used in combination with lithium (used in mental illnesses) it may cause a rise in blood levels of lithium and related side effects may be seen.

When used in combination with warfarin (a medicine which prevents blood clotting), the effects on bleeding in the gastrointestinal system increases.

Risk of kidney damage may increase when used in combination with cyclosporine and tacrolimus, medicines used to suppress the immune system.



The effect may reduce when used in combination with mifepristone, a medicine used to treat stomach and intestinal ulceration.

The group of medicines effective against pain, fever and inflammation including APRALJIN FORTE, may exacerbate heart failure, as they may increase the blood concentration of glycosides, medicines increasing the contraction of the heart, by affecting the elimination from the kidneys.

The group of medicines effective against pain, fever and inflammation including APRALJIN FORTE, may increase the risk of blood diseases, when used in combination with zidovudine, a medicine effective against retroviruses, including the virus causing human immune deficiency (HIV).

The group of medicines effective against pain, fever and inflammation including APRALJIN FORTE, may increase the risk of gastrointestinal bleeding when used in combination with SSRI's used to treat depression.

As with other medicines effective against pain, fever and inflammation, risk of gastrointestinal ulceration and bleeding increases when used in combination with steroids.

Animal studies showed that the risk of severe rhythmic contractions (convulsions) may increase in all or some of the voluntary muscles, when used in combination with quinolone group antibiotics.

Caution is advised when probenecid (a medicine that increases uric acid elimination) is used in combination as it may cause naproxen sodium have a higher effect in less time.

Care should be taken when used in combination with methotrexate (used to treat cancer). Naproxen sodium decreases elimination of methotrexate and therefore side effects of methotrexate may be seen.

Naproxen sodium should not be used for 8-12 days after mifepristone administration as Naproxen sodium can reduce the effects of mifepristone.

It may decrease the effect of beta blockers, used to treat high blood pressure. Naproxen sodium and other medicines effective against pain, fever and inflammation, may diminish the effects of medicines used to treat high blood pressure and may increase the kidney damage, caused by ACE inhibitors.

A with other medicines effective against pain, fever and inflammation, caution is advised when used in combination with oral contraceptives, due to the risk of gastrointestinal system ulceration and bleeding.

Please keep in mind that these warnings are also applicable to medicines used recently or about to be used in the future.

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

3. HOW TO TAKE APRALJIN FORTE?

Instructions for proper use and dose/administration frequency



The recommended initial dosage for APRALJIN FORTE is 1 tablet (550 mg), followed by 1 tablet every 12 hours or 275 mg every 6-8 hours. Initial daily total dosage should not exceed 1375 mg and then 2 tablets (1100 mg).

Route and method of administration

Swallow the tablets whole, on a full stomach, without chewing, with enough fluids, like a glass of water.

Different age groups

Use in children

APRALJIN FORTE is not advised in children less than 16 years of age. Only in children older than 5 years of age with juvenile arthritis, it can be used at a dosage of 10 mg/kg/day every 12 hours.

Use in elderly

The elimination of the medicine from the body in elderly patients could decrease, dosing should be made carefully and lowest effective dose should be used (65 years and older).

Use in special conditions

Kidney/Liver failure

You should not take APRALJIN FORTE if the results of your kidney function tests are not appropriate.

You should be careful when taking APRALJIN FORTE if you have impaired liver functions.

Please talk to your doctor or pharmacist if you have the impression that the effect of APRALJIN FORTE is too strong or too weak.

If you have taken more APRALJIN FORTE than you should

Distinct overdose symptoms are headache, dizziness, nausea, heartburn, indigestion, disorientation, vomiting, gastrointestinal bleeding, sometimes diarrhea, drowsiness, dizziness, ringing or buzzing in the ears, fainting. If too many tablets were taken accidentally or deliberately, stomach should be emptied and known supportive measures should be taken. Activated charcoal administration should be made within 1 hour after you have taken more APRALJIN FORTE than you should. Gastric lavage can be considered in adults. Frequent urination is advised. Your doctor will monitor your liver and kidney functions.

If you have taken more APRALJIN FORTE than you should, talk to a doctor or pharmacist.

If you forget to take APRALJIN FORTE

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

If you stop taking APRALJIN FORTE

No problems are to be expected after discontinuation of treatment.

4. POSSIBLE SIDE EFFECTS

Like all medicines, APRALJIN FORTE can cause side effects in patients with hypersensitivity to its ingredients.



If you get any of the followings, stop using APRALJIN FORTE and contact your doctor or go to your nearest hospital emergency department IMMEDIATELY:

- Swelling of the hands, ankles, face, mouth or throat causing difficulty in swallowing and breathing
- Wheezing or difficulty breathing (asthma attack)
- Fainting
- Skin rash
- A widespread fever and rash with blisters and peeling on your skin, mouth, around the genitalia, (Stevens-Johnson syndrome)
- Blisters or rash in various sizes on your mouth and other areas of your body (erythema multiforme)
- Toxic epidermal necrolysis characterized with fluid filled blisters on your skin, peeling of the skin and tissue loss.
- Severe headache, stiffness of the neck, nausea, vomiting and disorientation (aseptic meningitis)
- Blood or dark colored pieces that look like coffee ground in feces or vomit (gastrointestinal bleeding)

These are all very serious side effects.

If you have any of these, you are severely hypersensitive against APRALJIN FORTE. You may need emergency medical intervention or hospitalization.

These very serious side effects are very rare.

If you notice any of the following side effects, inform you doctor right away or go to the emergency room of the nearest hospital:

- Anemia due to deficiency of some blood cells, decrease in the number of white cells in the blood, decrease in the number of platelets involved in blood clotting
- Increase in blood sodium level
- Depression, sleep disturbance, insomnia
- Convulsions, coma, weakening of mental functions
- Edema of the visual nerve
- Hearing impairment, ringing or buzzing in the ears, dizziness
- High blood pressure, vascular occlusion
- Gastrointestinal disorders (indigestion, constipation, diarrhea, nausea, vomiting)
- Sweating, hair loss, skin problems and skin rashes, blisters
- Muscle aches and muscle weakness
- Infertility in women
- Feeling chills, fever, malaise
- Fatal hepatitis, jaundice (decreased appetite, fatigue, abnormalities in liver function tests)

These are all serious side effects. They require emergency medical intervention.

Serious side effects are seen very rare.

Inform your doctor if you notice any of the following side effects:

- Anemia
- Dizziness, lethargy, fatigue, headache, light sensitivity, attention deficit
- Drowsiness
- Hallucinations
- Blurred vision
- Palpitation
- Shortness of breath



- Ulceration and damage to the stomach, vomiting, diarrhea, abdominal pain, heartburn, constipation
- Itching, skin rash, marks or spots on the skin, bruising
- Kidney disorders
- Edema, feeling thirsty

These are mild side effects of APRALJIN FORTE.

If these effects do not pass by themselves or if they are severe or distressing, inform your doctor.

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 listed or not listed in this Patient Information Leaflet, talk to your doctor, pharmacist or nurse. In addition, you can report your side effects to Turkey Pharmacovigilance Center (TÜFAM) by directly clicking “Drug Side Effect Reporting” button at the web site of www.titck.gov.tr or you can call side effect reporting line at +90 800 314 00 08. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE APRALJIN FORTE

Keep APRALJIN FORTE out of the reach and sight of children and in its original package.

Store at room temperature below 30°C, protected from light.

Use it in accordance with the expiry date.

Do not use APRALJIN FORTE after the expiry date which is stated on the package.

Do not use APRALJIN FORTE if you notice any damage on product and/or package.

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.

Halkalı Merkez Mah. Basın Ekspres Cad. No: 1

34303 Küçükçekmece - ISTANBUL/TURKEY

Manufacturing Site:

DEVA Holding A.Ş.

Çerkezköy Organize Sanayi Bölgesi

Karaağaç Mah. Atatürk Cad., No: 32

Kapaklı - TEKIRDAG/TURKEY

This package leaflet was approved on 12.11.2021