

PATIENT INFORMATION LEAFLET

ELEKTRA® FORT 50 mg film coated tablet

For oral use.

Active Substance: Each film coated tablet contains 73.8 mg dexketoprofen trometamol equivalent to 50 mg dexketoprofen.

Excipients: Microcrystalline cellulose, maize starch, sodium starch glycollate, glycerol distearate, magnesium stearate, hypromellose, titanium dioxide, talc, polyethylene glycol.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this **PATIENT INFORMATION LEAFLET**. You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Please completely follow the instructions in this information leaflet. Do not use higher or lower doses other than what is recommended to you.*

In this leaflet:

- 1. What is ELEKTRA® FORT and what is it used for ?**
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1. What is ELEKTRA® FORT and what is it used for?

ELEKTRA® FORT is a pain killer from the group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).

It is indicated for the symptomatic treatment of osteoarthritis (joint destruction and calcification), rheumatoid arthritis (inflammatory joint disease) and ankylosing spondylitis (painful progressive rheumatism mostly with stiffness of spine joints) and the treatment of acute gouty arthritis (painful joint inflammation due to gout), acute musculoskeletal pain (eg back pain), postoperative pain and dysmenorrhea (painful menstrual periods).

ELEKTRA® FORT is available in packs containing 20 and 30 film coated tablets in white, opaque PVC/PE/PVDC/Al folio blisters.

ELEKTRA® FORT is white, round, biconvex film coated tablet scored on one side.

2. What you need to know before you take ELEKTRA® FORT?

Do not take ELEKTRA® FORT in the following conditions

If,

- You are allergic (hypersensitive) to dexketoprofen or any of the other ingredients of ELEKTRA® FORT;
- You are allergic to acetylsalicylic acid or to other non-steroidal anti-inflammatory medicines;
- You have asthma or have suffered attacks of asthma, acute allergic rhinitis (a short period of inflamed lining of the nose), nasal polyps (lumps within the nose due to allergy), urticaria (skin rash), swelling of the face and throat due to allergy (swollen face, eyes, lips, or tongue, or respiratory distress) or wheezing in the chest after taking acetylsalicylic acid or other non-steroidal anti-inflammatory medicines;
- You have suffered from photoallergic or phototoxic reactions (a particular form of reddening and/or blistering of the skin exposed to sunlight) while taking ketoprofen (a non-steroidal anti-inflammatory drug) or fibrates (drugs used to lower the level of fats in the blood);
- You have a peptic ulcer (gastrointestinal wound) stomach or bowel bleeding or chronic digestive problems (e.g. indigestion, heartburn) or if you have suffered in the past from stomach or bowel bleeding, ulceration or perforation;
- You have chronic digestive problems (e.g. indigestion, heartburn)
- You have suffered in the past from stomach or bowel bleeding or perforation, due to previous use of non-steroidal anti-inflammatory drugs (NSAIDs) used for pain;
- You have bowel disease with chronic inflammation (Crohn's disease or ulcerative colitis);
- You have serious heart failure, moderate or serious kidney problems or serious liver problems;
- You have a bleeding disorder or a blood clotting disorder;
- You are severely dehydrated (have lost a lot of body fluids) due to vomiting, diarrhea or insufficient intake of fluids;
- You are in the third trimester of pregnancy or breast feeding.
- If you have undergone coronary artery surgery (coronary artery by-pass graft), do not use for the treatment of pain before, during and after surgery.

Take special care with ELEKTRA® FORT in the following conditions

If,

- You suffer from allergy, or if you have had allergy problems in the past;
- You have kidney, liver or heart problems (hypertension and/or heart failure) as well as fluid retention, or have suffered from any of these problems in the past;

- You are taking diuretics or you suffer from very poor hydration and reduced blood volume due to an excessive loss of fluids (e.g. from excessive urination, diarrhea or vomiting);
- You have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist; Medicines such as ELEKTRA® FORT may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.
- You are elderly: you may be more likely to suffer from side effects (see section 4). If any of these occur, consult your doctor immediately;
- You are a woman with fertility problems (ELEKTRA® FORT may impair your fertility, therefore you should not take it if you are planning to become pregnant or you are doing fertility tests);
- You are in the first or second trimester of pregnancy;
- You suffer from a disorder in the formation of blood and blood cells;
- You have systemic lupus erythematosus (a disease manifested by widespread scaling of the skin) or mixed connective tissue disease (immune system disorders that affect connective tissue);
- You have suffered in the past from a chronic inflammatory disease of the bowel (ulcerative colitis, Crohn's disease);
- You have or have suffered in the past from other stomach or bowel problems;
- You have varicella (chickenpox), since exceptionally NSAIDs could worsen the infection;
- NSAIDs cause severe gastrointestinal system side effects that may be fatal, such as bleeding, gastrointestinal ulceration or perforation. These side effects can occur at any time with or without prior warning symptoms. Elderly are at higher risk of serious gastrointestinal system side effects.
- You are taking other medicines that increase the risk of peptic ulcer or bleeding, e.g. oral steroids, some antidepressants (those of the SSRI type, i.e. Selective Serotonin Reuptake Inhibitors), agents that prevent blood clots such as aspirin or anticoagulants such as warfarin. In such cases, consult your doctor before taking ELEKTRA® FORT. He/she may want you to take an additional medicine to protect your stomach (e.g. misoprostol or medicines that block the production of stomach acid).
- If you suffer from asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis due to the intake of acetylsalicylic acid or NSAIDs as you have a higher risk of allergy to acetylsalicylic acid and/or NSAIDs than the rest of the population. Administration of this medicine can cause asthma attacks or bronchospasm, particularly in patients allergic to acetylsalicylic acid or NSAIDs.

Please consult your doctor even if these warnings apply to you at any time in the past.

Taking ELEKTRA® FORT with food and drink

Take the film coated tablets with an adequate amount of water. Take the film coated tablets with food, as it helps to decrease the risk of stomach or bowel side effects. However, if you have acute pain, take the tablets on an empty stomach. When you take the medicine at least 30 minutes before meals, this helps the medicine start working a little faster.

Pregnancy

Before using this medicine consult your doctor or pharmacist.

Do not use ELEKTRA® FORT during the third trimester of pregnancy. It is best not to use ELEKTRA® FORT during the first or second trimester of pregnancy unless it is necessary. Tell your doctor if you are pregnant. If you are planning to get pregnant, ELEKTRA® FORT may not be right for you.

If you notice that you have been pregnant during treatment, consult immediately your doctor.

Breastfeeding

Before using this medicine consult your doctor or pharmacist.

Do not use ELEKTRA® FORT if you are breastfeeding.

Driving and using machinery

ELEKTRA® FORT may slightly affect your ability to drive and handle machines, due to the possibility of dizziness or drowsiness as side effects of treatment. If you notice such effects, do not drive or use machines until the symptoms wear off. Ask your doctor for advice.

Important information on some excipients present in ELEKTRA® FORT

No special warning for use.

Taking with other medicines

Always inform your doctor, dentist or pharmacist if you are using or receiving any of the following medicines in addition to ELEKTRA® FORT. There are some medicines that should not be taken together and others that may need their doses to be altered when taken together.

Inadvisable combinations:

- Acetylsalicylic acid (aspirin), corticosteroids (cortisone) or other anti-inflammatory drugs
- Warfarin, heparin or other medicines used to prevent blood clots
- Lithium, used to treat certain mood disorders
- Methotrexate used for the treatment of rheumatoid arthritis (a persistent disease causing pain and deformity in the joints) and cancer.
- Hydantoins and phenytoin, used for epilepsy
- Sulphamethoxazole, used for bacterial infections (suppurative microbial diseases)

Combinations requiring precautions:

- ACE inhibitors (eg enalapril, captopril), diuretics (eg, hydrocortiazide, furosemide), beta-blockers (eg metoprolol, atenolol) and angiotensin II antagonists (eg olmesartan, telmisartan) used for high blood pressure and heart problems
- Pentoxifylline and oxpentifylline, used to treat chronic venous ulcers
- Zidovudine, used to treat viral infections
- Aminoglycosides antibiotics (gentamicin, amikacin, etc.) used to treat bacterial infections
- Chlorpropamide and glibenclamide used for diabetes

Associations to be considered carefully:

- Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin) used for bacterial infections
- Cyclosporin or tacrolimus, used to treat immune system diseases and in organ transplant
- Streptokinase and other thrombolytic or fibrinolytic medicines, i.e. medicines used to break-up blood clots
- Probenecid, used in gout
- Digoxin, used to treat chronic heart failure
- Mifepristone used to terminate a pregnancy
- Antidepressants of the selective serotonin reuptake inhibitors type (SSRIs)
- Anti-platelet agents used to reduce platelet aggregation and the formation of blood clots

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

2. How to use ELEKTRA® FORT ?

Instructions for proper use and dosage/administration frequency:

Always take ELEKTRA® FORT exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose of ELEKTRA® FORT that you need depends on the type, severity and duration of your pain. Your doctor will tell you how many tablets you must take daily, and for how long. According to the nature and severity of pain, the recommended dosage is generally 75 mg (25 mg every 8 hours [1/2 film coated tablet]). The total daily dose should not exceed 75 mg.

Route and method of administration:

Take the film coated tablets with an adequate amount of water.

If your pain is intense and you need quicker relief, take the film coated tablet on an empty stomach (at least 30 minutes before food) because they will be more easily absorbed (See Section 2 “Taking ELEKTRA® FORT with food and drink”).

Different age groups:

Use in children and adolescents

ELEKTRA[®] FORT should not be used in children and adolescents.

In elderly

If you are elderly, you should start treatment with a total daily dose of no more than 1 film coated tablet (50 mg). In elderly patients this initial dose can later be increased to that generally recommended (75 mg) if ELEKTRA[®] FORT has been well tolerated.

Special conditions of use:

Renal / Hepatic Failure:

If you suffer from kidney or liver problems, you should start treatment with a total daily dose of no more than 1 film coated tablet (50 mg).

If you have the impression that the effect of ELEKTRA[®] FORT is too strong or weak, talk with your doctor or pharmacist.

If you take more ELEKTRA[®] FORT than you should:

If you used more ELEKTRA[®] FORT than was prescribed, tell your doctor or pharmacist.

Please remember to take this medicine pack or this leaflet with you.

If you forget to take ELEKTRA[®] FORT:

Take the next regular dose when it is due.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking ELEKTRA[®] FORT

No adverse effects are expected when treatment with ELEKTRA[®] FORT is discontinued.

4. Possible side effects

Like all medicines, ELEKTRA[®] FORT may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen, stop taking ELEKTRA[®] FORT and tell your doctor immediately or contact the casualty department at your nearest hospital

- Anaphylactic reaction (very severe response to allergy-causing substances of the body, sudden hypersensitivity)
- Open sores on skin, mouth, eyes and genital areas (Stevens Johnson and Lyell's syndromes)
- face swelling or swelling of the lips and throat (angioedema)
- breathlessness due to narrowing of the airways (bronchospasm)

These are all very serious side effects.

If you experience one of these side effects it means that you are severely allergic to ELEKTRA® FORT. You may need urgent medical attention or to be hospitalized.

These very serious side effects are all rare.

Very common: may be seen in at least 1 of 10 patients;

Common: may be seen in less than one of 10 patients but more than one of 100 patients;

Uncommon: may be seen in less than one of 100 patients but more than one of 1,000 patients;

Rare: may be seen in less than one of 1,000 patients but more than one of 10,000 patients;

Very rare: may be seen in at least one of 10,000 patients; Not known: Cannot be estimated from available data.

Common:

- Nausea and/or vomiting
- Abdominal pain
- Diarrhea
- Digestive problems (indigestion)

Uncommon:

- Dizziness (vertigo)
- Drowsiness
- Somnolence
- Disturbed sleep
- Nervousness
- Headache
- Palpitation
- Flushing
- Stomach problems
- Constipation
- Dry mouth
- Flatulence
- Skin rash
- Fatigue
- Pain
- Feeling feverish and shivering
- Generally feeling unwell, malaise

Rare:

- Peptic ulcer
- Peptic ulcer perforation or bleeding which may be seen as vomiting blood or black stools

- Fainting
- High blood pressure
- Too-slow breathing
- Water retention and peripheral swelling (e.g. swollen ankles)
- Loss of appetite (anorexia)
- Abnormal sensation
- Swelling of the larynx (laryngeal edema)
- Sudden kidney disorder (acute renal failure)
- liver cell injury (hepatitis)
- Itchy rash
- Acne
- Increased sweating
- Back pain
- Frequent urination
- Menstrual disorders
- Prostate problems
- Abnormal liver function tests (blood tests)

Very rare:

- Shortness of breath
- Fast heartbeat
- Low blood pressure
- Inflammation of the pancreas,
- Liver cell injury (hepatitis)
- Blurred vision
- Ringing in the ears (tinnitus)
- Sensitive skin
- Sensitivity to light
- Itching
- Kidney problems
- Reduced white blood cell count (neutropenia), fewer platelets in the blood (thrombocytopenia)

If you have previously suffered from any such side effects due to long-term use of anti-inflammatory drugs and especially if you are elderly, if you notice any stomach/bowel side effects at the start of treatment (e.g. stomach pain, heartburn or bleeding).

Stop using ELEKTRA® FORT as soon as you notice the appearance of a skin rash, or any lesion inside the mouth or on the genitals, or any sign of an allergy.

During treatment with non-steroidal anti-inflammatory drugs, fluid retention and swelling (especially in the ankles and legs), increased blood pressure and heart failure have been reported.

Medicines such as ELEKTRA® FORT may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

In patients with immune system disorders that affect connective tissue (systemic lupus erythematosus or mixed connective tissue disease), anti-inflammatory medicines may rarely cause fever, headache and neck stiffness.

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

5. How to store ELEKTRA® FORT?

Store ELEKTRA® FORT in its original packaging and keep out of the reach and sight of children.

Store at room temperature below 25°C protecting from light.

Use in compliance with the expiry date.

Do not use ELEKTRA® FORT after the expiry date which is stated on the packaging.

Do not use ELEKTRA® FORT if you notice defects on the product and/or its packaging.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

Santa Farma İlaç San. A.Ş.

Okmeydanı, Boruçiçeği Sokak, No: 16 34382 Şişli- İSTANBUL

Tel: (+90 212) 220 64 00

Fax: (+90 212) 222 57 59

Manufacturing Site:

Santa Farma İlaç San. A.Ş. GEBKİM 41455 Dilovası - KOCAELİ

Tel: (+90 262) 674 23 00

Fax: (+90 262) 674 23 21

This leaflet has been approved <{DD month YYYY}>. [To be completed nationally]