PACKAGE LEAFLET: INFORMATION FOR THE USER

ZADA PHARMACEUTICALS

Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or your pharmacist. This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

PRODOL® film-coated tablets 200 mg
PRODOL® film-coated tablets 400 mg
etodolac

In this leaflet:

1. What PRODOL film-coated tablets are and what they are used for?
PRODOL film-coated tablets belong to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs).
PRODOL film-coated tablets are used to relieve some of the symptoms caused by arthritis (Osteoarthritis and Rheumatoid arthritis) such as inflammation, swelling, stiffness and joint pain.

2. Before you take PRODOL film-coated tablets
Do not take **PRODOL** film-coated tablets if you
- are allergic (hypersensitive) to etodolac or any of the ingredients of **PRODOL** film-coated tablets (see section 6).
- have had an allergic reaction after taking aspirin, ibuprofen or other non-steroidal anti inflammatory drugs (NSAIDs). An allergic reaction may include swelling of the face or throat, a nettle rash, asthma or itchy and runny nose.
- have a peptic ulcer (a hole in the stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding.
- have had perforation related to previous non-steroidal anti-inflammatory drugs therapy
- have a severe heart failure, liver or renal failure
- are in the last three months of pregnancy (last trimester)

Take special care with PRODOL film-coated tablets
Tell your doctor or pharmacist before taking **PRODOL** film-coated tablets if you:
- have any kidney or liver problems or heart problems, especially if you are also taking diuretics (water tablets) and are elderly. The dose should be as low as possible and you should have regular checks
- have a blood disorder
- have high blood pressure or heart failure
- suffer from fluid retention (swelling of legs, ankles, or feet)
- have or had bronchial asthma or breathing difficulties
- suffer from auto-immune disorders such as mixed connective tissue disease, systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).

Important information about your medicine
Medicines such as **PRODOL** 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.
Please speak to your doctor if you have any factors that may put you at a greater risk of suffering a heart attack or stroke such as:
- you are a smoker
- you have any heart problems
- you have high cholesterol
- you have high blood pressure
- you have diabetes

If you are told you need a blood test or urine test, tell your doctor you are taking **PRODOL** film-coated tablets as the drug may affect the results.
Serious gastrointestinal side effects such as bleeding, ulceration and perforation can occur at any time with or without warning symptoms in patients treated with NSAIDs. If any sign of gastrointestinal bleeding occurs, **PRODOL** film-coated tablets should be stopped immediately.

Serious skin reactions including allergic reactions such as extensive rash, peeling or blistering of the skin, continuous itching may appear during the early course of the therapy or within the first month of treatment. These reactions have been reported very rarely with the use of NSAIDs. If any sign of skin reactions occurs **PRODOL** film-coated tablets should be stopped immediately.

Taking other medicines
Please inform your doctor pharmacist if you are taking, or have recently taken, any other medicines, including medicines/obtained without a prescription
Do not take **PRODOL** film-coated tablets in combination with:
- other non-steroidal anti-inflammatory drugs (NSAIDs) such as aspirin or ibuprofen

Care is needed if you are taking
- anti-coagulants such as warfarin (used to prevent blood clotting)
- ciclosporin, tacrolimus (used to help with organ transplants)
- cardiac glycosides such as digoxin (used to treat certain heart problems)
- lithium (used to treat manic depression)
- mifepristone (used to terminate pregnancy)
- methotrexate (used to treat conditions such as cancer, or rheumatoid arthritis)
- anti-hypertensives such as diuretics, also called water tablets (medicines used to treat high blood pressure)
- antibiotics known as quinolone such as ciprofloxacin, ofloxacin or levofloxacin
- corticosteroids (used to treat skin rashes)
- zidovudine (used to treat HIV infection)
- anti-platelet medicines such as clopidogrel, ticlopidine (used to prevent blood clots)
- selective serotonin reuptake inhibitor such as sertraline, fluoxetine (medicines used to treat certain brain disorders).

Taking PRODOL film-coated tablets with alcohol
Do not take alcohol while taking **PRODOL**. Stomach problems may be more likely to occur if you drink alcoholic beverages while being treated with this medicine.

Pregnancy and breast-feeding
Do not take **PRODOL** film-coated tablets if you are pregnant, may be pregnant or are breast-feeding.
PRODOL film-coated tablets may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
PRODOL film-coated tablets may cause dizziness, drowsiness or visual disturbances in some individuals. DO NOT drive or operate machines if you are affected.
Important information about some of the ingredients of **PRODOL** film-coated tablets

This medicine contains a small amount of an inactive ingredient lactose. 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 PRODOL film-coated tablets
Always take **PRODOL** film-coated tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with the medicine. The dose and manner of treatment will be determined only by your doctor.

Take **PRODOL** film-coated tablets by mouth with water. Take with or after food.
Always use the medicine according to your doctor's instructions.

The usual standard dose is:
Anti-rheumatic:
initial treatment with 800-1200 mg per day divided into 2-4 doses followed by maintenance therapy at the dosage of 600-1200 mg per day divided into 2-4 doses.
Pain relief:
initial treatment with 400 mg per day followed by 200-400 mg every 6-8 hours or 600
mg twice a day, followed by 600 mg 1-2 times per day, as required.
Do not exceed the dose of 1200 mg per day!

If you are an elderly person, your doctor will make sure that you take the lowest dose for the
shortest period of time due to the risk of severe side effects.
Children:
PRODOL film-coated tablets are not recommended for use in children.
If you have any further questions on the use of this product, ask your doctor or pharmacist.
If you forget to take **PRODOL** film-coated tablets at the right time, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.
If you have taken more **PRODOL** film-coated tablets than you should, consult your doctor or go to the nearest hospital casualty department immediately. Take this leaflet with you so your doctor will know what you have taken.
Symptoms of overdose include headache, nausea, vomiting,

epigastric pain, passage of black tarry stools, diarrhoea, disorientation, excitation, drowsiness, dizziness, ringing in the ear, fainting, occasionally fits and coma. Kidney failure and liver damage have also been reported.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, **PRODOL** Film-coated tablets can cause side effects, although not everybody gets them.
These side effects may be temporary. However, you should tell your doctor if the side effects are troublesome, or last for more than a few days. Medicines such as **PRODOL** film-coated tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

Very serious side effects
If any of the following happen, stop taking **PRODOL** film-coated tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:
- serious allergic reaction which causes
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- aggravation of asthma, asthma like reaction comprising of breathlessness, wheezing, feeling of tightness in the chest and shortness of breath
- different kind of skin disorders such as rashes, itching, hives, unusual bleeding or bruising under the skin, flaking or peeling of the skin
- serious illness with blistering of the skin, mouth, eyes and genitals
- gastrointestinal bleeding (rectal bleeding, passage of black stools, vomiting of blood or material that looks like coffee grounds), severe abdominal or stomach pain. Gastrointestinal problems can occur in some individuals at any time following long-term treatment with this class of medicines (NSAIDs)

These side effects are very serious. You may need urgent medical attention.

Serious side effects
Tell your doctor as soon as possible or go to the casualty department at your nearest hospital if you notice any of the following:
- increases risk of bleeding or bruising. These symptoms may be due to reduction in blood platelets
- frequent infections such as fever, severe chills, sore throat or mouth ulcers due to lack of white blood cells
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light. These symptoms may be due to infection around the brain or spinal cord (meningitis). This side effect has been reported especially in patients having systemic lupus erythematosus (allergic condition which causes joint pain, skin rashes and fever) or mixed connective tissue disease.
- visual disturbances ,sudden dimming or loss of vision
- heart attack, heart problems which can cause shortness of breath or ankle swelling
- numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech. These symptoms may be due to damage to part of the brain caused by an interruption to its blood supply (stroke)
- worsening of symptoms of colitis [inflammation of the colon (large bowel)]. Symptoms are diarrhoea, usually with blood and mucus, stomach pain, fever
- worsening of symptoms of Crohn's disease (an inflammatory disease that can affect any part of the gastrointestinal tract). Symptoms are pain, fever, diarrhoea and loss of weight
- severe pain in the abdomen and back often with nausea and vomiting. These symptoms may be due to inflammation of the pancreas
- liver problems such as jaundice (yellowing of the skin or whites of the eyes), liver function problems
- urinary problems such as high blood pressure, feet swelling, passing little or no urine or passing blood. These might be a sign of kidney failure or toxicity.

Other side effects
Tell your doctor if you notice any of the following:
- mental depression, headache, dizziness, trouble in sleeping, confusion, seeing or hearing things that are not real (hallucination), disorientation, nervousness, drowsiness or light-headedness
- sensation of numbness or tingling over the limbs
- shakiness or tremor
- swelling of legs, ankles or feet
- high blood pressure, throbbing of heart (palpitation)
- loose stool (diarrhoea), feeling or being sick (nausea or vomiting), indigestion, stomach pain, heart burn, constipation, wind
- mouth ulcers and cold sores
- pain when passing urine, urinating more or less often than usual
- inflammation of blood vessels, often with skin rash
- increased sensitivity of the skin to sunlight
- generally feeling unwell, tiredness, unusual weakness, chills and fever.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store PRODOL film-coated tablets
Keep out of the reach and sight of children.
Store in the original package.
Do not use **PRODOL** film-coated tablets after the expiry date that is stated on the outer packaging.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information
What **PRODOL** film-coated tablets contain:
The active ingredient is etodolac.
PRODOL film-coated tablets 200 mg
Each tablet contains etodolac 200mg.

PRODOL film-coated tablets 400 mg
Each tablet contains etodolac 400mg.
The other inactive ingredients are: lactose monohydrate, microcrystalline cellulose, povidone, copovidone, sodium starch glycollate, magnesium stearate and silicon dioxide, colloidal.
Film: Aquapolish pink, purifired water.

Contents of the pack:
30 (3×10) film-coated tablets of 200 mg etodolac in PVC/PVDC blister in carton box.
30 (3×10) film-coated tablets of 400 mg etodolac in PVC/PVDC blister in carton box.

Marketing Authorisation Holder and Manufacturer
ZADA Pharmaceuticals d.o.o.
Donji Bistarac without number
75300 Lukavac
Bosnia and Herzegovina.