

## PATIENT INFORMATION LEAFLET

### ASEKET 25 mg/500 mg film coated tablet

#### For oral use.

- **Active substance:** Each film tablet contains 520.83 mg paracetamol DC 96% equivalent to 500 mg paracetamol and 36.9 mg dexketoprofen trometamol equivalent to 25 mg dexketoprofen.
- **Excipients:** Microcrystalline cellulose PH 102 (E460), colloidal silicone dioxide, lactose monohydrate (derived from cow milk), povidone, crospovidone, sodium starch glycolate, magnesium stearate, kollicoat IR, collodion VA 64, titanium dioxide (E171), kaolin (E559), sodium lauryl sulfate.

**Read all of this PATIENT INFORMATION 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 additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not give 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.*

#### **What is in this leaflet:**

1. *What is ASEKET and what is it used for?*
2. *Before you take ASEKET*
3. *How to take ASEKET ?*
4. *Possible side effects*
5. *How to store ASEKET?*

#### **1. What is ASEKET is and what is it used for?**

- ASEKET film coated tablet contains dexketoprofen trometamol and paracetamol as active substances.
- Dexketoprofen trometamol is trometamine salt of S-(+)-2-(3-benzoylphenyl) propionic acid, belongs to non-steroidal anti-inflammatory drugs NSAIDs groups, is a pain killer, anti-inflammatory and antipyretic.
- Paracetamol is used as pain killer in various pain treatment and used as pain killer and antipyretic in pyretic diseases.
- ASEKET is used,
  - In the treatment of Osteoarthritis symptoms and findings

-Treatment of signs and symptoms of rheumatoid arthritis, a continuous disease that causes pain and deformity in joints

- In the symptoms and findings ankylosing spondylitis (Painful progressive rheumatic disease with cramping in the back joints)

- In the treatment of acute gut arthritis (Joint inflammation seen in gout)

- In the treatment of acute musculoskeletal system pains

- In the treatment postoperative (after surgery) pain

- In the treatment of dysmenorrhea (painful period)

- ASEKET is marketed in transparent PVC/PVDC/Aluminium foil blister package containing 20 white, oblong, biconvex, film coated tablets.

## **2. Before you take ASEKET**

**DO NOT use ASEKET in the conditions stated below.**

If,

- You have a hypersensitivity (allergy) to dexketoprofen, paracetamol or any other components that ASEKET contains
- You are allergic to other non-steroidal anti-inflammatory medicines
- You are allergic to aspirin (acetylsalicylic acid)
- You have asthma or have suffered attacks of asthma, a short period of inflamed lining of the nose (acute allergic rhinitis), lumps within the nose due to allergy (nasal polyps), skin rash (urticaria), swollen face, and throat due to allergy (angioedema) or after taking aspirin (acetylsalicylic acid) and other non-steroidal anti-inflammatory drugs (NSAIDs) there is wheezing in the chest
- If you already have gastric ulcer/bleeding, complaints about digestive disorders, or if you have problems with the intestine (Crohn's disease or ulcerative colitis) caused by inflammation
- You have a stomach or bowel bleeding history
- You are using another drug containing paracetamol
- You have Glucose-6-phosphate dehydrogenase enzyme (G6PD) deficiency
- You have a bronchial asthma history
- You have serious heart failure, moderate and serious kidney problems or serious liver problems
- You have a blood clotting disorder
- You are pregnant or breast-feeding
- If you are to undergo coronary artery by-pass graft (CABG) surgery to correct the obstruction of your heart vessels

**TAKE SPECIAL CARE with ASEKET 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 (oedema), or have suffered from any of these problems in the past
- You are taking diuretic medications or you suffer from very poor hydration and reduced

blood volume due to an excessive loss of fluids (e.g. from excessive urination, diarrhoea 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 ASEKET 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 especially gastro-intestinal (peptic ulcer) bleeding and perforation, which can be life threatening (see section 4). If any of these occur, consult your doctor immediately.
- You are a woman with fertility problems (ASEKET 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, planning to become pregnant
- You are breast-feeding
- You suffer from a disorder in the formation of blood and blood cells
- You have anemia
- If you have systemic lupus erythematosus, a disease that manifests with extensive scaling of the skin, or immune system disorders (mixed collagen tissue disease) that can affect collagen 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 and bowel problems
- You are taking other medicines that increase the risk of gastro-intestinal (peptic ulcer) or bleeding, e.g. oral steroids used orally, 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 ASEKET: Your doctor may want you to take an additional medicine to protect your stomach (e.g. misoprostol or medicines that block the production of stomach acid).
- You experience any of the following during your treatment, stop to take medicine and urgently request medical help: dark blood coming from feces, blood vomiting or dark pieces like coffee grounds
- You have indigestion or burning sensation, abdominal pain or other abnormal abdominal symptoms, stop taking the medicine and consult your doctor.
- You have lung disease
- You drink alcohol
- You use other medicines including especially painkillers

These alerts at any time in the past even if it is true for you, please consult your doctor.

### **Using ASEKET with food and drink**

Take ASEKET 30 minutes before the meal due to delaying the absorption rate while taking with food. The concurrent administration of the drug with food containing high carbohydrate (flour, sugar) may decrease its efficacy.

### **Pregnancy**

*Ask your doctor or pharmacist for advice before using the medicine.*

ASEKET should not be used during pregnancy term.

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

### **Breast-feeding**

*Ask your doctor or pharmacist for advice before using the medicine.*

Do not use ASEKET during breast-feeding period.

### **Driving and using machines**

ASEKET may slightly affect from mild or moderate your ability to drive and handle machines, due to the possibility of dizziness or drowsiness as side effects of treatment. You must be careful when using the machine or vehicle, or avoiding the use of the machine or vehicle.

### **Important information about on some of the ingredient of ASEKET**

This medicine contains less than 1 mmol (23 mg) sodium in each film coated tablet; no negative effect is expected from sodium as a cause of dose is expected.

ASEKET contains lactose monohydrate, so, if you were previously told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **Using with other medicines**

Some medicines shouldn't be used together or in case of concurrent usage dosages should be adjusted.

- Acetylsalicylic acid (aspirin), corticosteroids or salicylate, anti-inflammatory drugs (drugs used in treatment of inflammation) (NSAIDs)
- Lithium, used to treat certain mood disorders
- Methotrexate, a drug used in the treatment of rheumatoid arthritis, which is a continuous disease that causes pain and malformation in cancer and joints
- Hydantoins and phenytoin drugs used in the treatment of epilepsy
- Sulfamethoxazole drug used in the treatment of bacterial infections
- ACE inhibitors, diuretics, beta-blockers and angiotensin II antagonists, used for high blood pressure and heart problems
- Pentoxifylline and oxpentifylline, used to treat chronic venous ulcers
- Zidovudine, used to treat viral infections
- Chlorpropamide and glibenclamide, used for diabetes
- Quinolone antibiotics (e.g. ciprofloxacin, levofloxacin) used for bacterial infections
- Cyclosporine and tacrolimus, used to treat immune system diseases or in organ transplant
- Streptokinase and other thrombolytic or fibrinolytic medicines, i.e. medicines used to break-up blood clots
- Probenecid, used in the treatment of gout disease
- Digoxin, used to treat chronic heart failure
- Mifepristone, used as an abortifacient (to terminate a pregnancy)
- Drugs called selective serotonin reuptake inhibitors used in the treatment of depression
- Carbamazepine, barbiturates, primidone drugs used in seizure treatment, rifampicin, a kind of antibiotic
- Macrolide group antibiotics, anabolizane type drugs that stimulate protein production, cholesterol lowering statin group drugs, ethionamide used in the treatment of tuberculosis, isoniazid, cholesterol lowering niacin, phenothiazines used in the treatment of some psychological disorders

- Diflunisal (drug used in pain treatment)
- Cholestyramine (drug used in high cholesterol)
- Gastrokinetic drugs (metoclopramide and domperidone) that accelerate gastric motility
- Herbal products containing willow (hibiscus), echinacea (echinacea angustifolia), willow (contains pava (piper methysticum) and salicylate (salix alba)) and meadow (spiraea ulmaria)
- Warfarin, heparin, coumarin and indandion drugs to prevent blood clotting
- Herbal products containing Ginkgo (Ginkgo biloba), ginseng (Panax ginseng), garlic (Allium sativum), blueberries (Vaccinium myrtillis), chrysanthemum parthenium
- Herbal products such as yellow chamomile (Anthemis nobilis), horse chestnut (Aesculus hippocastanum), greek clover (Trigonella foenum graecum), red clover (Trifolium pratense) and tamarind (Tamarindus indicus)
- Drug called furosemide used in edema treatment

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

### 3. How to use ASEKET?

- **Instructions for appropriate method and dose/frequency of administration:**

Always use ASEKET exactly as your doctor has told you.

Your doctor will define and administrate the dose of your medicine according to the severity and type of pain.

The recommended dose according to the severity and type of pain is one film coated tablet three times in a day (one in 8 hours).

Total daily dose of dexketoprofen shouldn't be over 75 mg, total daily dose of paracetamol shouldn't be over 4 g.

Do not use ASEKET over subsequent three days without a doctor recommendation.

- **Route and method of administration:**

ASEKET is orally administrated.

It is recommended to be administrated in fasting condition at least 30 minutes before meal.

Take ASEKET with adequate amount of water.

- **Different age groups:**

#### **Use in children:**

Do not use ASEKET in children.

#### **Use in elderly (above 65 ages):**

The recommended starting dose in elder is two tablets in a day. Your doctor can increase your dose to 3 tablets per day according to your response to the treatment. Do not take more than 2 tablets per day unless otherwise your doctor adjust your dosage.

- **Special populations:**

#### **Kidney Failure:**

In the patients with mild renal function disorder, the recommended starting dose is two tablets per day. You should not take ASEKET in patients with moderate or severe renal function disorder.

**Liver Failure:**

In the patients with mild liver function disorder, the recommended starting dose is two tablets per day. You should not take ASEKET in patients with moderate or severe liver function disorder.

*If you have the impression that effect of ASEKET is too weak or strong, talk to your physician or pharmacist about it.*

**If you take more ASEKET than you should**

*If you have used more than you should from ASEKET, talk to a physician or a pharmacist.*

**If you forget to take ASEKET**

*Do not take a double dose to balance out the forgotten dose.*

Skip the dose that you forgot to take and take the next dose as usual. If you forgot to take multiple doses inform your doctor.

**Possible effects may occur when you stop taking ASEKET:**

If you face any problem about taking ASEKET, consult to your doctor or pharmacist.

You can stop using ASEKET by consulting your doctor.

**4. Possible side effects**

Like all medicines, side effects can be seen in people who are sensitive to substances in the content of ASEKET.

Side effects were listed as shown in the following categories:

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

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

**If any of the following takes place, stop taking ASEKET and immediately contact your physician or apply to the emergency department of the nearest hospital:**

- Anaphylactic reaction (sudden excessive sensitivity reaction)
- Face swelling or swelling of the throat (angio-neurotic edema)
- Stevens-Johnson syndrome, an inflammatory disease with blood clots, swelling and redness around the skin and the eye
- Toxic epidermal necrolysis (a serious disease with liquid filled blister on skin)
- Fainting
- Heart beat

These are all very serious side effects. If one of these exists in you, then you have a serious allergy against ASEKET. You may need to be admitted to an emergency medical intervention or hospital.

These very severe side effects have been seen quite rarely.

**If you experience any of the following side effects, immediately contact your physician or apply to the emergency department of the nearest hospital:**

- Abnormality in liver function tests
- Being sensitive to the light (photosensitive reactions)
- Kidney inflammation
- Pancreas inflammation
- Stomach and bowel infection appears with diarrhea and vomit
- Stomach ulcer, stomach ulcer bleeding
- Hypotension
- Hypertension
- Decrease in respiratory frequency
- Shortness of breath, difficulty in breathing
- Fast heartbeat
- Paresthesia
- Reduced white blood cell count
- Fewer platelets in the blood
- Dizziness due to balance disorder (vertigo)
- Ringing in the ears
- Upper respiratory tract infection

These are all severe side effects. Emergency medical intervention may be necessary. Severe side effects have been seen quite rare.

**Tell your doctor if you notice any of the following:**

**Common**

- Headache, dizziness, sleepiness
- Constipation
- Swelling in stomach-bowel due to gas
- Nausea and/or vomiting, stomachache, diarrhea
- Dyspepsia

**Uncommon**

- Tiredness, pain, weakness, shivering, dejection
- Skin redness
- Dryness of the mouth
- Incubus
- Insomnia

**Rare**

- Frequency in urinate
- Back pain
- Menstrual disorder, prostate problems
- Rash
- Acne
- Increase in sweatiness
- Inappetency

**Very rare**

- Itching
- Tinnitus
- Blurred vision

These are mild side effects of ASEKET.

*If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.*

**5. How to store ASEKET?**

*Store ASEKET in the package and keep out of the reach and sight of children.*

Store at room temperature below 25°C.

**Use in accordance with the expiry date.**

*Do not use ASEKET after the expiry date which is stated on the blister or package.*

If you notice decomposition in the product and/or its package, do not use ASEKET.

***Marketing authorization holder:***

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

[info@berko.com.tr](mailto:info@berko.com.tr)

***Manufacturer:***

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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