

PATIENT INFORMATION LEAFLET

ASEKET 25 mg/500 mg film tablets

For oral use.

- **Active substance:** Each film tablet contains 500 mg paracetamol and 36.9 mg dexketoprofen trometamol equivalent to 25 mg dexketoprofen.
- **Excipients:** Microcrystalline cellulose (E460), colloidal silicone dioxide, pregelatinized starch, sodium starch glycolate, magnesium stearate, partially hydrolysed polyvinyl alcohol, titanium dioxide (E171), polyethylene glycol (macrogol) and talc.

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

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

- ASEKET film 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
 - in the treatment of signs and symptoms of rheumatoid arthritis, a continuous disease that causes pain and deformity in joints
 - in the treatment of signs and findings of 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 tablets.

2. What you need to know before you take ASEKET ?

DO NOT use ASEKET

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

Warnings and precautions

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
- It should be used with caution under doctor control in patients with anemia, lung disease, liver and kidney dysfunction.
- 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 faeces, 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
- It causes serious liver toxicity when given (acute) high doses.
- It may cause liver damage in adults at long-term (chronic) daily doses.
- It should be used with caution in alcoholic liver patients.
- You use other medicines including painkillers

The daily dose of paracetamol should not exceed 2000 mg due to the risk of hepatotoxicity in alcohol users.

In patients who use paracetamol for the first time or have a history of previous use, redness, rash or a skin reaction may occur at the first dose or repeated doses. In this case, the use of the drug should be discontinued by contacting your doctor. The person who has a skin reaction with paracetamol should not use this medication or any other medication containing paracetamol. This may cause skin disorders including fatal Steven Johnson Syndrome (SJS-serious drug reaction involving the skin and mucous membranes, commonly characterized by the formation of blisters on the skin and deterioration of skin integrity), toxic epidermal necrolysis (TEN-blisters on the skin), and acute generalized exanthematous pustulosis (AGEP- a clinical presentation characterized by a pustule of skin containing an inflamed fluid on the widespread reddened skin and accompanied by high fever, often developing rapidly and shortly after drug use).

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

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

Consult your doctor or pharmacist before taking this medicine.

ASEKET should not be used during pregnancy term.

Consult your doctor or pharmacist immediately if you recognize that you are pregnant during your treatment.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Do not use ASEKET during breast-feeding period.

Driving and using machines

ASEKET may have mild or moderate effects on the ability to drive or use the machine due to the possibility of dizziness and drowsiness. You should be careful while driving or using machines or avoid the using machines or driving.

Important information about on some of the ingredient of ASEKET

There is no specific warning regarding the excipients it contains.

Other medicines and ASEKET

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 oedema treatment

If you currently have been receiving or have recently received any prescription or nonprescription medicine, please notify your doctor or pharmacist about these.

3. How to use ASEKET?

- **Instructions for use and dosage/frequency of administration:**

Always use this medicine exactly as your doctor has told you.

Your doctor will determine 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 tablet three times in a day (every 8 hours).

The total daily dose of dexketoprofen should not exceed 75 mg and the total daily dose of paracetamol should not exceed 4 g.

The daily dose of paracetamol should not exceed 2000 mg due to the risk of hepatotoxicity in alcohol users.

Do not use ASEKET for more than three consecutive days without medical advice.

- **Route of administration and method:**

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 cases of use:**

Renal Failure:

In the patients with mild renal function disorder, the recommended starting dose is two tablets per day. Do not use ASEKET if you have moderate or severe renal dysfunction.

Hepatic Failure:

In the patients with mild liver function disorder, the recommended starting dose is two tablets per day. Do not use ASEKET if you have severe hepatic dysfunction.

If you have impression that the effect of ASEKET is very strong or weak, tell a doctor or pharmacist.

If you take more ASEKET than you should

If you take more ASEKET than you should, tell your doctor or pharmacist.

If you forget to take ASEKET

Do not take a double dose to make up for a 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 experience any problems with the use of ASEKET, consult your doctor or pharmacist. You can stop using ASEKET by consulting your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects were listed by frequency as following:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

Rare: may affect up to 1 in 1,000 people

Very rare: may affect up to 1 in 10,000 people

Not known: frequency cannot be estimated from the available data.

If you notice any of the followings stop taking ASEKET and immediately inform your doctor or go to the nearest emergency department:

- Anaphylactic reaction (sudden excessive sensitivity reaction)
- Face swelling or swelling of the throat (allergic edema, angio-edema, angio-neurotic edema) due to allergy
- Fainting
- Heart beat
- Rash
- Itching
- Urticaria
- Acute generalized exanthematous pustulosis (a clinical presentation characterized by a pustule of skin containing an inflamed fluid on the widespread reddened skin and accompanied by high fever, often developing rapidly and shortly after drug use)

- Hypersensitivity to lace-like redness of hands, face and feet (erythema multiforme)
- Steven Johnson Syndrome (serious drug reaction involving the skin and mucous membranes, commonly characterized by the formation of blisters on the skin and deterioration of skin integrity)
- Toxic epidermal necrolysis (Lyell's syndrome), a severe disease of the skin with blisters (including fatal consequences)

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.

If you notice any of the followings immediately inform your doctor or go to the nearest emergency department:

- Abnormality in liver function tests
- Photosensitive reactions (being sensitive to the light)
- Kidney inflammation
- Pancreas inflammation
- Stomach and bowel infection appears with diarrhea and vomiting
- 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
- Vertigo (dizziness due to balance disorder)
- Ringing in the ears
- Upper respiratory tract infection

These are all severe side effects. Emergency medical intervention may be necessary.

If you experience any one of the followings tell your doctor:

- Headache, dizziness, sleepiness
- Tiredness, pain, weakness, shivering, dejection
- Itching
- Frequency in urinate
- Back pain
- Menstrual disorder, prostate problems
- Skin redness
- Acne
- Increase in sweatiness
- Constipation
- Dryness of the mouth
- Swelling in stomach-bowel due to gas
- Nausea and/or vomiting, abdominal pain, diarrhoea
- Tinnitus
- Dyspepsia

- Incubus
- Blurred vision
- Loss of appetite
- Insomnia

These are mild side effects of ASEKET.

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

5. How to store ASEKET?

Keep this medicine out of the sight and reach of children.

Store in the original package at room temperature below 25°C and protect from light.

Use in accordance with expiry date.

Do not use this medicine after the expiry date which is stated on the package.

Do not use this medicine if you notice defects in the product and / or packaging.

Marketing authorization holder:

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