PACKAGE LEAFLET: INFORMATION FOR THE USER

DEKLARIT 500 mg Film Coated Tablets
Taken by mouth

Active substance: Each tablet contains 500 mg clarithromycin.
Excipients: Croscarmellose sodium, microcrystalline cellulose, polyvinylpyrrolidone, colloidal silicon dioxide, magnesium stearate, talc.
Film coating agent: Opadry 03B 22320 yellow (Indigo carmine, tartrazine, hydroxypropyl-methylcellulose, polyethylene glycol, titanium dioxide)

Read all of this PACKAGE LEAFLET carefully before you start using 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.*
- *During the period when you take this medicine, tell your doctor that you take this drug 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 for this medicine.*

In this leaflet:
1. What DEKLARIT is and what it is used for
2. Before you take DEKLARIT
3. How to take DEKLARIT
4. Possible side effects
5. How to store DEKLARIT

1. WHAT DEKLARIT IS AND WHAT IT IS USED FOR

DEKLARIT Film Coated Tablets are yellow film-coated, homogenous, oblong tablets scored in the middle on one side. They are presented in blister packages with 14 tablets in one box.
Each DEKLARIT Film Coated Tablet contains 500 mg clarithromycin.

DEKLARIT (clarithromycin) is a semi-synthetic antibiotic which belongs to a group called macrolides. Clarithromycin exerts its effect against bacteria by inhibition of protein synthesis in susceptible bacteria.

DEKLARIT is used to treat following infections caused by various microorganisms in adults and children 12 years of age and older:
- Upper respiratory tract infections such as pharyngitis (pharynx inflammation), tonsillitis (tonsil inflammation), acute maxillary sinusitis (sinus inflammation),
- Lower respiratory tract infections such as acute bacterial exacerbation of chronic bronchitis, pneumonia,
- Uncomplicated several skin and soft tissue infection
- Infections caused by a special type of bacteria called mycobacterium.

DEKLARIT is also used for following cases:

- For prevention of an infection caused by a type of mycobacterium (*Mycobacterium avium* complex) in patients with AIDS (acquired immune deficiency syndrome),
- For eradication of bacteria called *H. pylori* for reducing the recurrence of duodenal ulcer,
- For treatment of dental infections.

2. BEFORE YOU TAKE DEKLARIT

DO NOT take DEKLARIT, if:

- You are allergic (hypersensitive) to clarithromycin, erythromycin or antibiotics of macrolides group and also to any of the other ingredients of DEKLARIT.
- You are taking any of the following drugs: astemizole (used for hay fever or allergy), cisapride (used for stomach disease), pimozide (used to treat some psychiatric diseases), terfenadine (used for hay fever or allergy), ergotamine (used for migraine), dihydroergotamine (used for migraine), lovastatin or simvastatin (used to treat high cholesterol).
- You are using colchicine (a drug used to treat gout (drop) disease, familial Mediterranean fever and Behçet's disease) while you have kidney or liver disease.
- You are using a medicine containing midazolam (sedative) and which is taken orally.
- You have history of QT prolongation (changes in the electrical activity of the heart) or cardiac arrhythmia (prolonged QT syndrome/Torsades de Pointes).
- You have severe liver failure accompanied by kidney disorder.
- You have hypokalemia (low levels of potassium in the blood) or cardiac arrhythmia (palpitations), ask your doctor for advice.

TAKE SPECIAL CARE with DEKLARIT:

- If you have diarrhea or history of diarrhea during use of an antibiotic. With use of nearly all antibacterial drugs, intestinal inflammation (antibiotic-associated colitis “pseudomembranous colitis”) may occur which may range from mild to severe diarrhea.
- If you have severe renal impairment. In such case, your doctor may decide to reduce the dose or prolong the dose intervals. Caution should be taken if you have severe renal failure. However, no adjustment of dosage for DEKLARIT is necessary if you have normal renal function but hepatic impairment.
- If you are taking medicine containing colchicine. There have been reports of colchicine toxicity, especially in the elderly, some of which occurred in patients with renal insufficiency.
- If the symptoms of muscle weakness have exacerbated.
- If you have used clarithromycin for a long period of time; as it may lead to increase in number of non-susceptible bacteria and fungi, appropriate treatment must be initiated in case of superinfection.
- Concomitant use of clarithromycin and oral hypoglycemic agents (drugs which regulate blood sugar) and/or insulin may lead to significant decrease in blood sugar level. In such cases, glucose level is recommended to be carefully monitored.
- Co-administration of clarithromycin and warfarin (anti coagulant) leads to increased risk of serious bleeding and significant increase in prothrombin time. When clarithromycin and anticoagulant (drugs which prevent blood clotting) are concomitantly administered, coagulation time must be frequently checked.
- When statines (group of medicine used to lower cholesterol) are co-administered with clarithromycin, the lowest possible doses must be administered.
- Caution should be taken when clarithromycin is concomitantly administered with triazolam or midazolam (sedatives).

- Clarithromycin should be used with caution in patients with medical condition related to increased tendency to heart disorders such as QT prolongation and torsades de pointes due to risk for QT prolongation (changes in the electrical activity of the heart).
- Sensitivity testing should be performed when prescribing clarithromycin for treatment of community-acquired pneumonia.
- Sensitivity testing should be performed when prescribing clarithromycin for treatment of mild to moderate skin and soft tissue infections.

Warnings and precautions
Tell your doctor or pharmacist especially before using this medicine, if you have any heart disease or disorder.

Please inform your doctor or pharmacist is you have any heart disorder.

If these warnings are applicable to you, even for any period of time in past, please consult your doctor.

You may need to be treated for these diseases or your doctor may reduce the dose or may think that you need to stop the therapy immediately (*see section 4 Possible Side Effects).*

Important warning!
Antibacterial drugs including DEKLARIT, or in other words, antibiotics only should be used for treatment of bacterial infections. These drugs do not treat viral infections, like common cold. When DEKLARIT are prescribed for treatment of a bacterial infection, it is normal that patients feel well at the beginning of treatment; however, patients should not be deceived by this feeling and therefore treatment should not be discontinued prematurely; the term prescribed by the doctor must be definitely completed. Skipping a dose and incompletion of treatment term reduce the efficacy of current treatment and eliminate the treatability by DEKLARIT or other antibacterial drugs by increasing the possibility of development of resistance by bacteria.

Taking DEKLARIT with foods and drinks:
DEKLARIT can be taken on an empty or full stomach.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.
The safety of clarithromycin for use during pregnancy has not been established. Therefore; DEKLARIT is not recommended for use without a careful benefit/risk assessment. DEKLARIT should not be used during pregnancy except in clinical circumstances where no alternative therapy is appropriate. Your doctor will carefully assess the benefit/risk.

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

Breastfeeding
Consult your doctor or pharmacist before taking this medicine.
The safety of clarithromycin for use in breastfed infants has not been established.
You should not breastfeed while you are using DEKLARIT.

Driving and using machines
There are no data on the effect of DEKLARIT on the ability to drive and use machines. The potential for vertigo (dizziness), confusion and disorientation, which may occur with the medication, should be taken into account before patients drive and use machines.

Important information about some of ingredients of DEKLARIT
Each DEKLARIT Film Coated Tablet contains 6.68 mg sodium than 1 mmol (23 mg), not any sodium-related side effect is expected with this dose.
Each DEKLARIT Film Coated Tablet contains 0.92 mg tartrazine. It may cause allergic reactions.

Taking other medicines:
If you are taking any of the following drugs, you may need to change the dose and/or take other precautions, tell your doctor or pharmacist.

- If you are taking the following drugs, an increase may be observed in their blood levels: alfentanil (sedative), alprazolam (sedative), astemizole (a drug used for allergic conditions in respiratory system), bromocriptine (a drug used to treat some brain diseases and diabetes), digoxin (a drug used in heart diseases), disopyramide (a drug used to treat heart rhythm disorder), ergot alkaloids (drugs used to treat nervous system or genitourinary system diseases), phenytoin (a drug used to treat epilepsy), hexobarbital (sedative), carbamazepine (a drug used to treat epilepsy), quinidine (a drug used in heart diseases), lovastatin (a drug used to treat high cholesterol), methylprednisolone (a drug used for treatment of allergy and rheumatism), midazolam (sedative), omeprazole (a drug used to treat stomach ulcer and reflux disease), oral anticoagulants (drugs for thinning blood e.g. warfarin), pimozide (a drug used to treat nervous system diseases), rifabutin (a drug used to treat several infection diseases), sildenafil (a drug used to treat sexual dysfunction), cilostazol (a drug used to treat vascular diseases), cisapride (a drug used to treat digestive system diseases), ciclosporine (a drug used to prevent transplant rejection and to treat some rheumatic or eye diseases), simvastatin (drugs used to treat high cholesterol), sirolimus and tacrolimus (drugs used to prevent transplant rejection), theophylline (a drug used to treat respiratory system diseases), terfenadine (a drug used in allergic conditions in respiratory system), triazolam (a drug used in nervous system diseases), vinblastine (a drug used to treat some cancer diseases) and valproate (a drug used to treat epilepsy).
- Rifampicin (a type of antibiotic), phenytoin, carbamazepine and phenobarbital (drugs used to treat epilepsy), St John's Wort (a plant used as food supplement) may induce the metabolism of clarithromycin. This may result in sub-therapeutic levels of clarithromycin leading to reduced efficacy. Furthermore; it might be necessary to monitor the plasma levels of these drugs, which could be increased by clarithromycin.
- Concomitant administration of rifabutin (a drug used to treat infections caused by bacteria called mycobacteria) and clarithromycin resulted in an increase in rifabutin and decrease in clarithromycin serum levels together with an increased risk of uveitis.
- Co-administration of clarithromycin with zidovudine (a drug used to treat AIDS (HIV infection)) may result in decreased zidovudine concentrations.
- Caution should be exercised also with its co-administration with ritonavir (a drug used to treat AIDS (HIV) infection)); doses of clarithromycin higher than 1 g/day should not be co-administered with ritonavir. Similar dose adjustments should be considered in patients with reduced renal function when ritonavir is used as an enhancer with other HIV (AIDS) drugs including atazanavir and saquinavir.
- When clarithromycin was co-administered with these following drugs, heart rhythm disorders some of which may be life-threatening was observed especially in patients with heart disease: cisapride (a drug used to treat digestive system diseases), pimozide (a drug used to treat nervous

system diseases), terfenadine (a drug used to treat allergic respiratory tract diseases), quinidine (a drug used in some heart diseases) or disopyramide (a drug used to treat heart arrhythmia) (see section 2, Before you take DEKLARIT)

- Similar effects have been observed with concomitant administration of terfenadine and macrolid group antibiotics in patients with heart disease. The same effects have been also observed with concomitant administration of astemizole and other macrolides.
- Caution is advised regarding concomitant administration of clarithromycin with other ototoxic drugs which may cause damaging to hear, especially with aminoglycosides.
- When clarithromycin was co-administered with ergotamine or dihydroergotamine (drugs used to treat migraine), acute ergot toxicity occurred in some cases; therefore they should not be co-administered.
- Strong inducers of metabolism system, e.g. efavirenz, nevirapine, rifampicin, rifabutin and rifapentine may accelerate the metabolism of clarithromycin.
- Co-administration of clarithromycin with phosphodiesterase inhibitors such sildenafil, tadalafil or vardenafil (drugs used to treat sexual dysfunction) may lead to increased exposure. When clarithromycin is co-administered with sildenafil, tadalafil and vardenafil, reduction in doses of these drugs should be considered.
- Clarithromycin and atazanavir, itraconazole, saquinavir substrate and inhibitors (drugs used to treat fungal infection and human immunodeficiency virus) may lead to bidirectional drug interaction. Patients who concomitantly take these should be monitored for symptoms of increased or prolonged pharmacological effect.
- When clarithromycin is co-administered with colchicine (a drug used to treat gout (drop) disease, familial Mediterranean fever and Behçet's disease), colchicine toxicity occurred in some cases. In case of co-administration of clarithromycin with colchicine, caution should be exercised in respect of symptoms of this toxicity condition.
- In patients with severe renal impairment or history of acute porphyria, administration of clarithromycin with ranitidine bismuth citrate (a drug used to treat ulcer) treatment is not recommended.
- In cases of concomitant administration of clarithromycin and verapamil, amlodipine or diltiazem (drugs used to treat heart diseases and high blood pressure), lowered blood pressure, slowed heart beat and lactic acidosis were observed.
- Clarithromycin level was decreased by etravirine used to treat HIV (AIDS).
- If you are using following drugs, ask your doctor for advice: methylprednisolone (a drug used for treatment of allergy and rheumatism), vinblastine (a drug used to treat some cancer diseases), aprepitant (a drug used to prevent nausea that may occur during cancer treatment), cilostazol (a drug used to treat vascular diseases) or ciclosporine (a drug used to prevent transplant rejection and treatment of some rheumatic or eye diseases).

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 DEKLARIT

Instructions for proper use and dose/frequency of administration

- Your doctor will tell you how long to take DEKLARIT and how many tablets you should take at each dose. Always comply exactly with your doctor’s recommendations.
- If you are not sure about how you should take DEKLARIT, definitely consult your doctor.
- Usual recommended dose of DEKLARIT for adults is 250-500 mg twice daily (every 12 hours)

for 6–14 days or 7-14 days. Duration of treatment is longer for mycobacterial infections (3-4 weeks or longer) and in more severe cases, the dosage can be increased to 1000 mg daily. Your doctor will tell you the dose you need to take and how long you will take it according to the type of infection you have.

Dose in *H. pylori* eradication:
- 500 mg clarithromycin is taken 2-3 times daily for 7, 10, 14 or 28 days with other medicines according to the treatment regimen to be recommended by your doctor for H. pylori eradication on the prevention of recurrence of duodenal ulcer.

Route and method of administration:
- Care should be taken for swallowing DEKLARIT at 12-hour intervals in the morning and in the evening at the same time each day; so that, the amount of drug in your blood will be constant and regular all the time.
- Take DEKLARIT orally and swallow as a whole with sufficient amount of water (e.g. one glass of water). Do not chew or crush the tablets.
- Your doctor will tell you how long to take DEKLARIT. Do not interrupt your treatment even if you feel recovered.
- Do not forget to take your medicine on time.

Different age groups

Use in children
No clinical trials have been conducted using Clarithromycin 500 mg Tablets in children under 12 years of age and are therefore not recommended. Clarithromycin suspension forms are available for children under 12 years of age.

Use in elderly
Dose adjustment should be considered in elderly patients with severe kidney failure.

Use in special conditions

Kidney failure
In patients with significant renal impairment, the dosage of DEKLARIT should be reduced by half, that is 250 mg once daily, or 250 mg twice daily in more severe infections. Treatment should not be continued for more than 14 days in these patients. In patients with moderate kidney failure, maximum one 500 mg DEKLARIT should be taken daily.

Liver failure
DEKLARIT should be administered with caution to patients with liver failure.

If you have the impression that the effect of DEKLARIT is too strong or too weak, talk to your doctor or pharmacist.

If you take more DEKLARIT than you should:
If you have taken more DEKLARIT than you should, talk to your doctor or pharmacist.
Ingestion of large amounts of DEKLARIT is expected to produce gastro-intestinal symptoms. Allergic reactions may also occur in case of overdose.

If you forget to take DEKLARIT:
If you forget dose, take your tablet as soon as you remember. However, if it is time for the next dose, skip the forgotten dose and continue to take one dose daily as always.

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

If you stop taking DEKLARIT
Do not stop taking DEKLARIT, even if you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, DEKLARIT can cause side effects in patients with hypersensitivity to any of the ingredients.
Side effects are classified in the following frequencies:

Very common	: affects at least 1 in 10 patients
Common	: affects 1 to 10 patients in 100
Uncommon	: affects 1 to 10 patients in 1000
Rare	: affects 1 to 10 patients in 10.000
Very rare	: affects less than 1 patient in 10,000
Unknown	: cannot be estimated from the available data.

Following side effects may occur as a result of using of DEKLARIT:

If you have any of the following, stop taking DEKLARIT and tell your doctor IMMEDIATELY or go to the nearest hospital emergency department:
- Allergic reactions (small bruising and bleeding on skin) from hives and moderate skin rashes to anaphylaxis and serious skin reactions (toxic epidermal necrolysis/Stevens-Johnson Syndrome, DRESS and Henoch-Schonlein purpura)

Uncommon
- Palpitations
- Increased alanine aminotransferase (ALT) (liver enzymes)
- Increased aspartate aminotransferase (AST) (liver enzymes)
- Severe itching (pruritus)
- Hives (urticaria)
- Leukopenia (reduced number of leucocytes in blood, frequent infections)
- Neutropenia (severe decrease in number of neutrocytes in blood, frequent infections)
- Eosinophilia (severe increase in number of eosinophil leucocytes in blood, increase in allergic cases, itching, redness)
- Increased gamma glutamyl transferase

Unknown
- Increased liver enzymes and liver dysfunction with or without jaundice; signs and symptoms of liver inflammation such as anorexia (severe loss of appetite), jaundice, dark urine, itching or sensitivity in abdomen
- Increase in number of eosinophiles in blood (a type of allergy cell) and medicine reactions

associated with general symptoms
- Hypoglycemia in patients using blood sugar lowering medicines some of which are taken orally or under insulin treatment (lowered blood sugar)
- Severe heart rhythm disorder
- Pancreas inflammation (infection)
- Interstitial nephritis (type of renal inflammation)
- Colchicine toxicity especially in the elderly and some patients with renal insufficiency due to co-administration of clarithromycin and colchicine
- Skeletal muscle breakdown
- Pseudomembranous colitis (severe diarrhea)
- Erysipelas (acute febrile disease manifested as inflammatory redness on skin)
- Erythrasma (a skin disease manifested as reddish or brownish spots)
- Agranulocytosis (chills, high fever and formation of ulcers on mucosa)
- Myopathy (muscle pains, weakness)
- Renal failure

These are all very serious side effects. They may require urgent medical attention.

If you notice any of the following, tell your doctor immediately or go to the nearest hospital emergency department:
Uncommon
- Vertigo (dizziness)
- Inflammation of the tongue, inflammation of the mouth, oral thrush and discoloration of the tongue
- Decrease in white blood cell and platelet counts
- Increased blood urea and creatinine, increased liver enzymes
- Candidiasis (fungal infection caused by Candida)
- Vaginal infection
- Tremor (shaking)
- Hearing disorders
- Gastritis (heartburn after meal)
- Transient increases in liver enzymes
- Increased alkaline phosphatase in blood
- Increased lactate dehydrogenase in blood

Unknown
- Disorientation, hallucinations, depression, psychosis and depersonalization, mania (psychological disorder manifested as extreme happiness and confident behavior)
- Loss of hearing
- Convulsions (seizure)
- Muscle pain
- Feeling of numbness or tingling on any part of body (paresthesia)
- Bleeding (hemorrhage)
- Acne
- Increase in international normalized ratio (INR- a scale used to measure clotting time)
- Prolonged prothrombin (clotting) time (PTZ)
- Abnormal urine color

These are all serious side effects. They may require urgent medical attention.

If you notice any of the following, tell your doctor:
Common
- Diarrhea
- Vomiting
- Stomach pain
- Indigestion
- Nausea
- Insomnia

Uncommon
- Loss of appetite
- Constipation
- Dry mouth
- Abdominal distension
- Dizziness
- Anxiety and worry
- Ringing in the ear
- Shaking
- Weakness
- Chest pain
- Fatigue
- Belching

Unknown
- Behavioral change
- Nightmares
- Mental confusion
- Change in sense of smell accompanied with impaired taste
- Tooth discoloration

These side effects are mild side effects of DEKLARIT

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 including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly to Turkey Pharmacovigilance Center (TÜFAM) via clicking on the icon of 'Side Effect Reporting for Medicines' at www.titck.gov.tr or calling +90 800 314 00 08 as the line of side effect reporting. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DEKLARIT

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

Store DEKLARIT at room temperature below 30°C and in a dry place.

Use in line with expiry date.
Do not take DEKLARIT after the expiry date indicated on packaging.

Do not take DEKLARIT if you notice damage on product and/or its package.

Any unused solutions or waste material should be disposed of in accordance with local requirements.

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.

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