PACKAGE LEAFLET

TRIBEKSOL 250 mg / 250 mg / 1 mg Film Coated Tablets
Taken by mouth.

***Active substance*:** Each film-coated tablet contains 250 mg vitamin B_1 (thiamine mononitrate), 250 mg vitamin B_6 (pyridoxine hydrochloride) and 1 mg vitamin B_{12} (cyanocobalamin).
***Excipients*:** Povidone K 90 (Plasdone K 90), microcrystalline cellulose (Avicel pH 112 SLM), croscarmellose sodium (Ac-di-sol), anhydrous lactose (from cow's milk), magnesium stearate, Opadry 0Y 24931 pink (titanium dioxide, polyethylene glycol 400, ponceau 4R, indigocarmine, quinoline yellow).

***Read all of this PACKAGE 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 further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take this medicine in either **higher** or **lower** dose other than recommended to you.*

In this leaflet:

1. WHAT TRIBEKSOL IS AND WHAT IT IS USED FOR

TRIBEKSOL is available in packs of 30 or 50 tablets. Each tablet contains 250 mg vitamin B_1, 250 mg vitamin B_6 and 1 mg vitamin B_{12}.

- It is used in patients with combined deficiency or with risk factors for deficiency of vitamins B_1, B_6 and B_{12}.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TRIBEKSOL

DO NOT USE TRIBEKSOL in the following situations:
- If you are allergic to any of the ingredients of this medicine,
- If you are pregnant or breastfeeding,
- If you are under the age of 18,
- If you have liver or kidney failure

USE TRIBEKSOL CAREFULLY in the following situations:
- If you have Leber disease (hereditary reduction in optic nerve volume),
- If you have serious megaloblastic anemia (a type of anemia that develops as a result of vitamin B_{12} and/or folic acid deficiency),

Tumor (cancer) patients should only use TRIBEKSOL after consulting their doctor.

Since TRIBEKSOL contains vitamin B_6, it may negatively affect the efficacy of some medicines (such as levodopa) used for Parkinson's disease. Parkinson's patients should consult their doctor or pharmacist before using TRIBEKSOL or any other medicinal product containing vitamin B_6.

The recommended dose and treatment duration should not be exceeded. If not taken as recommended, overdose can lead to serious neurotoxicity (undesired harmful effect on the nervous system). If symptoms persist or get worse, consult your doctor.

If any of these warnings apply to you, even for a period in the past, please consult your doctor.

TRIBEKSOL with food and drinks
Alcohol intake can reduce blood levels of vitamins B_6 and B_{12}.

Pregnancy
Consult your doctor or pharmacist before using this medicine.
It should not be used during pregnancy. Women with childbearing potential must use an effective birth control method during treatment.

Tell your doctor or pharmacist immediately if you find out that you are pregnant during treatment.

Breastfeeding
Consult your doctor or pharmacist before using this medicine.
It should not be used during breastfeeding.

Driving and using machines
The product has no or negligible effects on the ability to drive and use machines.

Important information about some of the other ingredients of TRIBEKSOL
This medicinal product contains lactose anhydrous. If your doctor previously told you that you have intolerance to certain forms of sugar, talk to your doctor before taking this medicine.

This medicine may cause allergic reactions due to its excipient called ponceau 4R.

Using with other medicines
When used with certain medicines, the effects of TRIBEKSOL or the other medicine may change, or some side effects may increase. Please tell your doctor if you are using any of the following medicines:

- Thiosemicarbazone (an antiviral, antifungal and antibacterial medicine)
- 5-fluorouracil (for cancer treatment)
- Antacid (medicines used for heartburn and indigestion)
- Levodopa (used for Parkinson's disease)
- Cycloserine (an antibiotic)
- Hydralazine medicines (used for high blood pressure or heart failure)
- Isoniazid (used for tuberculosis)

- Deoxypyridoxine (vitamin B_6 antagonist (which blocks it or exerts an opposite effect), used to experimentally induce vitamin B_6 deficiency)
- D-penicillamine (an antibiotic)
- Birth-control pills
- Altretamine (used for the treatment of cancer)
- Phenobarbital (used for the treatment of epilepsy)
- Phenytoin (used for the treatment of epilepsy)
- Amiodarone (used for heart rhythm disorder)
- Chloramphenicol (a antibiotic)
- Alcohol
- Aminosalicylates (used for the treatment of inflammatory bowel diseases)
- Colchicine (used in rheumatic diseases), especially if used together with antibiotics called aminoglycosides
- Aminoglycoside antibiotics (such as amikacin, apramycin, geneticin (G418), gentamicin, kanamycin, netilmicin, neomycin, paromomycin, spectinomycin, streptomycin, tobramycin)
- Cholestyramine (used for lowering blood cholesterol (fat) amount)
- Potassium chloride (used to restore potassium deficiency)
- Methyldopa (used to treat high blood pressure)
- Cimetidine (used to treat excess stomach acid that causes indigestion or ulcers)
- Folic acid
- Histamine (H2) receptor antagonists (used for stomach disorders)
- Metformin and related biguanides (used for non-insulin dependent diabetes)
- Proton pump inhibitors (used for stomach disorders)
- Vitamin C

Effects on tests

- Vitamin B_1 may cause false positive results in the urobilinogen test using Ehrlich's reagent.
- High doses of vitamin B_1 may interfere with spectrophotometric determination of theophylline concentrations in blood.
- Urobilinogen: Vitamin B_6 may cause a false positive result in a spot test with Ehrlich reagent.

Please tell your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without a prescription.

3. HOW TO USE TRIBEKSOL

Instructions for proper use and dose/frequency of administration

The dose for adults is 1 film-coated tablet per day, unless your doctor recommends otherwise. The product is usually used for one to several weeks. In some cases, your doctor may extend the treatment period by several months.

Route and method of administration

TRIBEKSOL tablets should be swallowed whole with a sufficient amount of liquid and used at recommended doses.

Different age groups

Use in children

It should not be used in children and adolescents under 18 years of age.

Use in the elderly
No specific dose is recommended.

Use in special conditions
Liver / Kidney failure
It should not be used in patients with kidney or liver failure.

Tell your doctor or pharmacist if you think that effect of TRIBEKSOL is too strong or too weak.

If you use more TRIBEKSOL than you should
There is no evidence that this product can cause an overdose when used as recommended. Symptoms that may occur in case of an overdose are: nausea, headache, loss of sensation and coordination of movements as a result of nerve damage (sensory and/or peripheral neuropathy, neuropathy syndromes), sensory disorders such as numbness, tingling or burning sensation (paresthesia), sleepiness, increased blood AST level (an enzyme test often used for the diagnosis of heart and liver diseases) and decreased blood folic acid concentrations. The effects resolve if treatment is stopped.

If you have used more TRIBEKSOL than recommended, tell your doctor or pharmacist.

If you forget to use TRIBEKSOL
If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, then do not take the missed dose.
Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with TRIBEKSOL is stopped
There is no known effect.

4. POSSIBLE SIDE EFFECTS
Like all medicines, TRIBEKSOL may cause side effects in people sensitive to its ingredients.

The evaluation of undesirable effects is based on the following frequencies:
Very common : affects at least 1 in 10 patients.
Common : affects less than 1 in 10 patients, but 1 or more than 1 in 100 patients.
Uncommon : affects less than 1 in 100 patients, but 1 or more than 1 in 1,000 patients.
Rare : affects less than 1 in 1,000 patients, but 1 or more than 1 in 10,000 patients.
Very rare : affects less than 1 in 10,000 patients.
Not known : Cannot be established with available data.

If you get any of the following symptoms, stop using TRIBEKSOL and IMMEDIATELY tell your doctor or refer to the nearest hospital's emergency department:
Allergic reactions
- Redness and blisters filled with water (hives)
- Rashes
- Face swelling
- Difficulty breathing with wheezing
- Skin lumps
- Swelling of the skin
- Photosensitive skin reactions

- Difficulty breathing
- Chest tightness

These are all very serious side effects with unknown frequency. If you have any of them, you are seriously allergic to TRIBEKSOL. You may need immediate medical intervention or hospitalization.

Other side effects:
Rare
- A skin rash characterized by raised, itchy and red spots (Urticaria exanthema)
- A skin rash with sudden onset, widespread over body, and characterized by numerous, small, pus-filled vesicles on the red and edematous skin (Exanthematous rash)
- Disease that may progress with swelling (edema) on the skin and internal organs (Angioedema)

Not known
- Dizziness
- Headache
- Peripheral neuropathy (conditions that occur when nerves connecting to the brain and spinal cord from other parts of the body are damaged or diseased)
- Polyneuropathy (a disease or disorder that spreads to many nerves, which occurs with numbness, tingling and paresthesias in the arms and legs, and can sometimes cause loss of function)
- Somnolence (a state of semi-conscious sleep that is not very deep, or a tendency to sleep)
- Paresthesia (a sensory organ disorder that occurs in the perception of touch, pain, temperature or vibration stimuli)
- Increased aspartate aminotransferase (increase in the values of the enzyme called Aspartate aminotransferase (ASP-SGOT) after a tissue damage in the liver, heart, muscle tissue, kidney or brain)
- Decrease in blood folate levels (Decrease in the blood serum level of folate, a water-soluble vitamin B, in cases where the cell division rate is high, such as alcoholism, pregnancy, anemia, cancer, or in case of its insufficient intake from the diet)
- Hypotonia (loss of muscle tone).
- Diarrhea
- Indigestion
- Nausea, vomiting
- Stomach and abdominal pain
- Abnormal urine odor
- High doses may cause acne.

If you notice any side effects not listed in this leaflet, please inform 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 via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRIBEKSOL

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

Store at room temperature below 25°C. Keep away from humidity.

Do not open the blister pack until you are ready to take the medicine.

Use it in accordance with its expiry date.

Do not use TRIBEKSOL after its expiration date that is marked on the packaging.

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.

Marketing Authorization Holder
DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturer
DEVA Holding A.Ş.
Kapaklı – TEKİRDAĞ / TÜRKİYE

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