PATIENT INFORMATION LEAFLET

INDURIN 1.5 mg sustained release film coated tablet
Taken by mouth

• ***Active substance:*** Each film coated table contains 1.5 mg indapamide as active ingredient.

• ***Inactive substance:*** Colloidal anhydride silica, lactose monohydrate, pregelatinized corn starch, magnesium stearate, hydroxypropyl methyl cellulose, propylene methyl cellulose, polyethylene glycol 6000, titanium dioxide (E171)

Read all of this 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, please ask to your doctor or pharmacist.

• This medicine is prescribed only for you. Do not pass it on to others.

• If you visit a doctor or hospital during usage of this medicine, please give information to your doctor that you are taking this medicine.

*• Please strictly follow instructions in this prescribing leaflet. Do not take **lower or higher** dose than recommended dose.*

What is in this leaflet:

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

- INDURIN tablets are supplied in a round, white blister package of 30 and 90 tablets for sustained release.
- INDURIN is prescribed by your doctor for the treatment of essential hypertension.
- It is a medicine for lowering high blood pressure and it contains indapamide. Many diuretics increase the amount of urine in the kidneys. However, indapamide is slightly different. Because it increases the amount of urine in the kidneys very little.

2. Things to consider before you start to take INDURIN

DO NOT TAKE INDURIN in the following situations:

- If you have an excessive allergy to the active substance, any of the excipients, or sulfonamide derivatives,
- If you have severe kidney failure,
- If you have severe hepatic impairment or hepatic encephalopathy,
- If you have hypokalemia

USE CAREFULLY INDURIN in the following situations:

- If you have liver disease,
- If you have diabetes diseases,
- If you have gout diseases,
- If you have arrhythmia or kidney diseases
- If you need to check that the parathyroid gland is working properly.

Tell your doctor if you have had a sensitivity to light reaction before**.**

Your doctor may require blood tests to check for low sodium and potassium or high calcium levels in the blood.

The active ingredient of this drug may react positively during antidoping tests. Athletes need to be careful.

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

Usage of INDURIN with food and drink

You can take INDURIN on an empty or full stomach.

Pregnancy

Ask a doctor or pharmacist before taking the medicine.

Tell your doctor if you are pregnant or planning a pregnancy. It is not known whether INDURIN has an effect on unborn babies.

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

Breast feeding

Ask a doctor or pharmacist before taking the medicine.

INDURIN is not recommended to be used during breastfeeding due to the transition to breast milk.

Usage of machine or vehicle

INDURIN has no stimulant effect, but dizziness or fatigue may occur at the start of treatment or when the dose is increased due to a drop in blood pressure. Therefore, care must be taken when driving and operating machinery.

Important information about some of the inactive ingredients of INDURIN

This medicine contains 104.50 mg lactose. If you have previously been told by your doctor that you have intolerance to certain sugars, you should consult your doctor before taking this medicinal product.

INDURIN contains titanium dioxide (E171). It may cause allergic reactions.

Taking other medicines

INDURIN not used with lithium. (a drug used to treat depression)

Tell your doctor if you are taking any of the following medications:

- Medications for heart rhythm disorders (eg. kinidin, hydrokinidin, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, dijitalis)
- Drugs used in the treatment of mental illnesses such as depression, anxiety, schizophrenia
- Bepridil (treatment of angina pectoris causing chest pain)
- Kisaprid, diphemanil (treatment of gastro-intestinal disorders)
- Sparfloksasin, moksifloksasin (infection-treating antibiotic)
- Halofantrin (treatment of some types of malaria)
- Pentamidin (treatment of pneumonia)
- Mizolastine (treatment of allergic reactions such as hay fever)
- Steroid-free anti-inflammatory drugs used as painkillers (ibuprofen) or high dose salicylates (aspirin)

- Angiotensin converting enzyme inhibitors (high blood pressure and heart failure treatment)
- Oral corticosteroids (severe asthma or rheumatoid arthritis disease)
- Stimulant laxative
- Baclofen (treatment of muscle stiffness in diseases such as multiple sclerosis-MS-)
- Potassium sparing diuretics (spironolactone, amiloride, triamterene)
- Metformin (diabetes disease)
- Iodine-containing contrast agent (X-ray tests)
- Calcium tablets or other calcium supplements
- In the treatment of autoimmune disorders or to prevent rejection after organ transplant surgery, or serious rheumatism (cyclosporine, tacrolimus or other drugs)
- Tetrakozaktid (Crohn treatment)

Please inform your doctor or pharmacist if you are using or have recently used any medicine with or without a prescription.

3. How to take INDURIN?

Instructions for proper use and dose / application frequency:

The recommended dose of INDURIN is one tablet in the morning. Due to the diuretic effect, it is recommended that you take INDURIN in the morning to avoid interrupting your night's sleep.

Tablets can be taken on an empty or full stomach.

Aplication form and method:

IJNDURIN is taken orally. Swallow the tablet with sufficient amount of water without chewing and breaking.

Different age groups:

Use of children:

INDURIN is not recommended for use by children and adolescents.

Use of elderly:

Elderly patients can be treated with INDURIN if their kidney function is normal or only slightly impaired.

Special use cases:

Kidney failure:

Treatment in patients with severe kidney insufficiency is contraindicated.

Liver failure:

Treatment in patients with severe liver insufficiency is contraindicated.

Unless your doctor recommends otherwise follow these instructions.

If you have impression for effect of the INDURIN for being too strong or weak, consult to your doctor or pharmacist.

If you use more INDURIN than you need:

If you have an impression that you took INDURIN more than you need, talk to your doctor or pharmacist.

High levels of INDURIN may cause nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys.

If you forget to use INDURIN:

Do not take double doses to compensate for forgotten doses.

You should use your medicine every day. Treatment is more effective when used regularly.

Possible effects of termination of treatment with INDURIN

Treatment of hypertension is a long-term treatment. Check with your doctor before stopping using this medicine.

4. What are possible side effect?

Like all medicines, INDURIN can have side effects on persons who are sensitive to the materials in its content.

Side effects are classified as following categories:

Very common : minimum 1 in 10 patients are affected

Common : fewer than 1 in 10, but more than 1 in 100 patients are affected

Uncommon : fewer than 1 in 100, but more than 1 in 1000 patients are affected

Rare : fewer than 1 in 1000 patients are affected

Very rare : fewer than 1 in 10,000 patients are affected

Not known : frequency cannot be estimated from the available data

Common:

- Maculopapular rash

Uncommon:

- Vomiting
- Allergic symptom in the skin and skin rash. Purpurea (small red point in the skin)

Rare:

- Dizziness, headache, fatigue and paresthesia (numbness or tingling in hands and feet)
- Gastrointestinal disorders (such as nausea, constipation), dry mouth
- Increased risk of dehydration in the elderly and patients with heart failure

Very rare:

- Irregular heartbeat, low blood pressure
- Kidney disorders,
- Pancreatitis (inflammation of the pancreas)
- Impairment in the liver functions
- Changes in blood cells such as thrombocytopenia
- Easy bruising of skin and nosebleed
- Leucopenia (decrease in white blood cells, unexplained fever, sore throat and other flu symptoms), anemia
- Angioedema or urticaria, severe skin reactions Severe itching or severe skin rash on swelling of the face, lips, mouth, tongue or throat making it difficult to swallow or breathe. In such cases, contact your doctor immediately.
- Increased calcium level in the blood.

Unknown:

Changes in laboratory parameters (blood tests) may occur. In this case, your doctor may ask for blood tests. The following laboratory parameters may change:

- Decrease in the level of potassium salt in the blood, may cause muscle weakening.
- Lowering the sodium salt level in the blood can cause loss of water and low blood pressure.
- Increasing uric acid can be cause gout diseases (pain in the joints).
- Increasing blood sugar in the patients with diabetes.

- Increase in liver enzyme levels
- Abnormal EKG results
- Life-threatening irregular heartbeat (Torsade de Pointes)
- Hepatitis
- Faintness
- This can be worse if you have collagen vascular disorder such as systemic lupus erythematous.
- Sensitivity after exposure to sun or artificial UVA rays (change in skin appearance)
- Onset of hepatic encephalopathy can be seen if there is liver failure (impaired brain function due to hepatic insufficiency)

If you get any side effects not listed in this leaflet, please give information to your doctor or pharmacist.

Reporting side effects

Talk to your doctor, pharmacist or nurse if you have any side effects that are included or not in the leaflet. Also report any side effect you may encounter to the "Drug Side Effects Report" at www.titck.gov.tr or call 0 800 314 00 08 “Turkey Pharmacovigilance Center (TUFAM)” side effect notification line. By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

5. How to store INDURIN?

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

Keep this medicine at room temperature lower than 25°C.

Use as agreeable with expiration dates.

Do not use INDURIN after the expiration date on the packaging.

If you notice any defects in the product and/or package, do not use INDURIN.

Do not throw away drugs that have expired or are not used! Give to the collection system determined by the Ministry of Environment and Urbanism.

Registration Holder: Terra İlaç ve Kimya San. Tic.A.Ş.
Ümraniye/İstanbul

Manufacturer: Pharmavision Sanayi ve Tic. A.Ş.
Topkapı / İstanbul

This leaflet is approved on 23.11.2017