



## PACKAGE LEAFLET: INFORMATION FOR THE USER

### COLASTIN-L 20 mg Film Coated Tablets Taken by mouth.

**Active substance:** Each film coated tablet contains 21.651 mg atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin.

**Excipients:** Lactose monohydrate (obtained from bovine milk), calcium carbonate, microcrystalline cellulose PH101, microcrystalline cellulose PH102, croscarmellose sodium, hydroxypropyl cellulose-L, polysorbate 80, magnesium stearate,

**Film-coating agents:** Opadry YS-1-7040 White (Hydroxypropyl methyl cellulose, polyethylene glycol, titanium dioxide, talc), simethicone emulsion

**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 a 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.*

#### **In this leaflet:**

- 1. What COLASTIN-L is and what it is used for***
- 2. What you need to know before you take COLASTIN-L***
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- 4. Possible side effects***
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### **1. WHAT COLASTIN-L IS AND WHAT IT IS USED FOR**

Each film coated tablet is presented for use in blister packages of 30 and 90 tablets containing atorvastatin calcium trihydrate equivalent to 20 mg atorvastatin and titanium dioxide as coloring agent.

COLASTIN-L are white, homogenous, film-coated oblong tablets embossed “20” on one side. COLASTIN-L belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

Atorvastatin is used to lower lipids known as cholesterol and triglycerides. Cholesterol is a naturally occurrence substance necessary for normal growth. However; if there is too much cholesterol in blood, it can be deposited in the walls of blood vessels leading to narrowing of these vessels, which may become blocked. This is one of the most common causes of heart disease. It is accepted that raised cholesterol levels increase the risk of heart disease.

COLASTIN-L is used to lower lipids known as cholesterol and triglycerides in the blood when a low fat diet and life style changes on their own have failed.



If you are at an increased risk of heart disease, COLASTIN-L can also be used to reduce such risk even if your cholesterol levels are normal. You should maintain a standard cholesterol lowering diet during treatment.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COLASTIN-L**

### **DO NOT TAKE COLASTIN-L**

- if you are allergic to atorvastatin or any of the other ingredients of this medicine
- if you have or have ever had a disease which affects the liver
- if you have had any unexplained abnormal blood tests for liver function
- if you are a woman able to have children and not using reliable contraception
- if you are pregnant or trying to become pregnant
- if you are breast-feeding
- if you use the combination of glecaprevir/pibrentasvir in the treatment of hepatitis C

### **TAKE SPECIAL CARE with COLASTIN-L, if**

- You have kidney problems or history of kidney problems,
- You have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems
- You have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes
- You have had previous muscular problems (muscular pain, weakness etc.) during treatment with other lipid-lowering medicines (e.g. statin or fibrate medicines),
- You regularly drink a large amount of alcohol,
- You have an intolerance to some sugars,
- You have serious problems with your breathing,
- You have hypothyroidism (under-active thyroid gland),
- You are older than 70 years,
- You have risk factors for diabetes. If you have diabetes or at risk for developing diabetes; your doctor will closely monitor you while you are taking this medicine. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.
- You are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and COLASTIN-L can lead to serious muscle problems (rhabdomyolysis)

If any of these apply to you, your doctor will need to carry out a blood test before and during your COLASTIN-L treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant. Additional tests and medicines may be needed to diagnose and treat this.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.



Tell your doctor if you have ever had a stroke, your doctor will need to consider this in deciding the best treatment and dose for you.

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

### **Taking COLASTIN-L with food and drink**

#### *Grapefruit juice*

Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of COLASTIN-L.

#### *Alcohol*

Avoid drinking too much alcohol while taking this medicine. See section 2 “Warnings and precautions” for details.

### **Pregnancy**

*Consult your doctor or pharmacist before taking this medicine.*

Do not take COLASTIN-L if you are pregnant, or if you are trying to become pregnant.

Do not take COLASTIN-L if you are able to become pregnant unless you use reliable contraceptive measures.

Do not take COLASTIN-L if you are breast-feeding.

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

### **Breast-Feeding**

*Consult your doctor or pharmacist before taking this medicine.*

Do not take COLASTIN-L if you are breast-feeding. The safety of COLASTIN-L during pregnancy and breast-feeding has not yet been proven.

### **Driving and using machines**

It is not expected that COLASTIN-L has any negative effect on ability to drive and operate machines. Do not drive if this medicine affects your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

### **Important information about some of the ingredients of COLASTIN-L**

COLASTIN-L contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that may change the effect of COLASTIN-L or their effect may be changed by COLASTIN-L. This type of interaction could make one or both of the medicines less effective. Alternatively it could increase the risk or severity of side-effects, including the important muscle wasting condition known as rhabdomyolysis described in section 4:

- Medicines used to alter the way your immune system works, e.g. ciclosporin
- Certain antibiotics or antifungal medicines, e.g. erythromycin, clarithromycin, telithromycin, ketoconazole, itraconazole, voriconazole, fluconazole, posaconazole, rifampin, fusidic acid
- Other medicines to regulate lipid levels, e.g. gemfibrozil, other fibrates, colestipol
- Some calcium channel blockers used for angina or high blood pressure, e.g. amlodipine, diltiazem; medicines to regulate your heart rhythm e.g. digoxin, verapamil, amiodarone
- Letemovir, a medicine that helps stop you from getting ill from cytomegalovirus

- Medicines used in the treatment of HIV e.g. ritonavir, lopinavir, atazanavir, indinavir, darunavir, the combination of tipranavir/ritonavir etc.
- Some medicines used in the treatment of hepatitis C e.g. telaprevir, boceprevir and the combination of elbasvir/grazoprevir
- Other medicines known to interact with COLASTIN-L include
  - ezetimibe (which lowers cholesterol),
  - warfarin (which reduces blood clotting),
  - oral contraceptives
  - stiripentol (an anti-convulsant for epilepsy)
  - cimetidine (used for heartburn and peptic ulcers)
  - phenazone (a painkiller)
  - colchicine (used to treat gout)
  - antacids (indigestion products containing aluminum or magnesium)
- Medicines obtained without a prescription: St John's Wort
- If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart COLASTIN-L. Taking COLASTIN-L with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

*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 COLASTIN-L**

#### **Instructions for proper use and dose/administration frequency:**

- The usual starting dose of COLASTIN-L is 10 mg in adults and children aged 10 years and older.
- This may be increased if necessary by your doctor until you are taking the amount you need. Your doctor will control and adapt the dose at intervals of 4 weeks or more. The maximum dose of COLASTIN-L is 80 mg once daily.
- Before starting COLASTIN-L treatment, a low-cholesterol diet should be initiated and this diet should be continued also during COLASTIN-L treatment.
- Always take COLASTIN-L exactly as your doctor has told you. You should check with your doctor and pharmacist if you are not sure.

#### **Route and method of administration:**

- COLASTIN-L should be swallowed whole with a drink of water.
- Doses can be taken at any time of day, with or without food.
- However, try to take your dose at the same time every day.

#### **Different age groups**

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

The recommended starting dose is 10 mg for children aged 10 years and older, the maximum recommended dose is 80 mg daily.

##### **Use in elderly:**

No difference in efficacy, safety and achievement of lipid treatment goals of COLASTIN-L was observed between elderly patients and general population.



## Use in special conditions

### **Kidney failure:**

Dose adjustment in patients with renal impairment is not necessary.

### **Liver failure:**

COLASTIN-L should not be used in patients with active liver disease. It should be used with caution in patients who have a history of liver disease. Liver function tests should be performed before the initiation of treatment with COLASTIN-L and periodically thereafter.

*If you have an impression that the effect of COLASTIN-L is too strong or weak, talk to your doctor or pharmacist.*

### **If you take more COLASTIN-L than you should:**

*If you have taken more COLASTIN-L than you should, talk to your doctor or pharmacist.*

### **If you forget to take COLASTIN-L**

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.

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

### **If you stop taking COLASTIN-L**

If you have further questions regarding the possible effects when you stop taking COLASTIN-L, regarding the use of this medicine or wish to stop your treatment, talk to your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, COLASTIN-L can cause side effects in patients with hypersensitivity to its ingredients.

**If you get any of the followings, stop taking COLASTIN-L and contact your doctor or go your nearest hospital emergency department IMMEDIATELY:**

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

- Angioneurotic edema (swelling of the face, tongue and throat that can cause great difficulty in breathing). This serious side effect occurs very rarely. If you have any of these, inform your doctor immediately.
- Serious illness with severe peeling and swelling of the skin, blistering of the skin, mouth, eyes, genitals and fever.
- Skin rash with pink-red blotches on palms of hands or soles of feet which may blister.
- Muscle weakness, tenderness, pain, rupture or red-brown discolouration of urine and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis). The abnormal muscle breakdown does not always go away, even after you have stopped taking atorvastatin, and it can be life-threatening and lead to kidney problems.

Tell your doctor immediately if you have muscle problems that persist even after your doctor has advised you to stop taking COLASTIN-L. In such case, your doctor may do further tests to diagnose the cause of your muscle problems.

**Very rare conditions:** Affect less than 1 in 10,000 patients taking COLASTIN-L (this means that for every 10,000 patients taking COLASTIN-L, 9,999 are not expected to experience these side effects.)

- If you experience problems with unexpected or unusual bleeding or bruising, this may be suggestive of a liver complaint. Your doctor should do blood tests to check your liver before you start taking COLASTIN-L or if you have symptoms of liver problems while you take COLASTIN-L. If you have the following symptoms suggestive of liver problems, inform your doctor right away:
  - Feel tired or weak
  - Loss of appetite
  - Upper belly pain
  - Dark amber-colored urine
  - Yellowing of your skin or the whites of your eyes
- Stevens-Johnson syndrome (serious blistering of the skin, mouth, eyes and genitals), erythema multiforme (patchy red rash), visual disturbance, blurred vision, hearing loss, tendon injury, liver failure, change in sense of taste, breast enlargement in men.
- Lupus-like disease syndrome (including rash, joint disorders and effects on blood cells).

These are all very serious side effects.

If you have any of these, you may need emergency medical intervention or hospitalization. All of these very serious side effects occur very rarely.

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.

### **Other possible side effects:**

#### **Common side effects**

- Inflammation of nasal passages, pain in the throat, nose-bleeding
- Allergic reactions
- Increases in blood sugar levels (if you have diabetes, continue careful monitoring of your blood sugar levels), increase in blood creatinine kinase
- Headache
- Nausea, constipation, flatulence, indigestion, diarrhea
- Joint pain, muscle pain and back pain
- Blood test results that show your liver function can become abnormal

#### **Uncommon side effects**

- Anorexia (loss of appetite), weight gain, decreases in blood sugar levels (if you have diabetes, you should continue careful monitoring of your blood sugar levels)



- Having nightmares, insomnia
- Dizziness, numbness or tingling in the fingers and toes, reductions of sensation to pain or touch, change in sense of taste, loss of memory
- Blurred vision
- Ringing in the ears and/or head
- Vomiting, belching, abdominal pain upper and lower, pancreatitis (inflammation of pancreas leading to stomach pain)
- Hepatitis (liver inflammation)
- Skin rash and itching, hives, hair loss
- Neck pain, muscle fatigue
- Fatigue, feeling unwell, weakness, chest pain, swelling especially in the ankles (edema), raised temperature
- Urine tests that are positive for white blood cells

#### **Rare side effects**

- Visual disturbance
- Unexpected bleeding or bruising
- Cholestasis (yellowing of the skin and whites of the eyes)
- Tendon injury

#### **Very rare side effects**

- An allergic reaction – symptoms may include sudden wheezing and chest pain or tightness, swelling of the eyelids, face, lips, mouth, tongue and throat, difficulty breathing, collapse
- Hearing loss
- Gynecomasty (breast enlargement in men and women)

#### **Unknown**

- Muscle weakness that is constant.

Possible side effects reported with some statins (medicines of the same type):

- Sleep disturbances including insomnia and nightmares, memory loss (confusion)
- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or fever
- Diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

#### 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](http://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.

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

## **5. HOW TO STORE COLASTIN-L**



*Keep COLASTIN-L out of the reach and sight of children and in its original package.*

Store at room temperature below 25°C.

**Take this medicine in accordance with the expiry date.**

*Do not take COLASTIN-L after the expiry date which is stated on the package.*

If you notice any damage on product and/or package, do not take COLASTIN-L.

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:***

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