Do not take Atorvastatin Tablets:

- If you are allergic to atorvastatin or any of the other ingredients of this medicine.
- If you have ever had an allergic reaction to any of the medicines in this group (e.g. -statin or -fibrate medicines)
- If you have or have ever had a disease that affects the liver.
- If you have or have ever had unexplained muscle aches or pains, a personal history of muscle wasting condition known as rhabdomyolysis. (listed in section 4).

Tell your doctor or pharmacist if you:

- Are older than 70 years.
- Have a history of liver disease.
- Have an under-active thyroid gland.
- Have kidney problems.
- Have had a previous stroke with remaining neurologic deficits.
- Are pregnant or breast-feeding.
- Have or have ever had a disease that affects your ability to drive. Do not use any machines that require you to maintain your balance.
- Have had a previous episode of unexplained muscle problems (rhabdomyolysis).
- Have had a personal history of myasthenia gravis.
- Have or have ever had serious muscle problems (rhabdomyolysis). Ask your doctor or pharmacist for advice before taking any medicine.
- Drink large amounts of alcohol.
- Have a history of epilepsy, or are a car driver.
- Have ever had a seizure.
- Are on medicines known as statins, which are lipid lowering medicines (e.g. simvastatin, pravastatin, lovastatin).

Before starting treatment, your doctor will tell you when it is safe to restart treatment with fusidic acid. They will also tell you how to treat a bacterial infection you will need to keep taking the medicine. Your doctor will tell you when it is safe to restart Atorvastatin treatment. Atorvastatin Tablets with fusidic acid may rarely lead to muscle weakness or pain (rhabdomyolysis). See more information regarding rhabdomyolysis in section 4.

Do not take Atorvastatin Tablets if you are pregnant or breast-feeding.

The safety of Atorvastatin Tablets during pregnancy and breast-feeding has not yet been proven. Do not take this medicine if you are planning to become pregnant.

Driving and using machines

Normally this medicine does not affect your ability to drive or use machines. However, if you get side-effects that affect your ability to drive. Do not use any tools or machines if your ability to use them is affected by this medicine.

Atorvastatin Tablets contain paracetamol:
- 10, 20 and 40 mg tablets contain less than 5 mg sodium, i.e. essentially ‘sodium-free’.
- ‘Bilang tablets’ contain 5 mg sodium (main component of coating salt) in each tablet. The maximum dose of Atorvastatin Tablets is 0.5 mg a day. Your doctor will tell you when it is safe to restart treatment with fusidic acid. They will also tell you how to treat a bacterial infection you will need to keep taking the medicine. Your doctor will tell you when it is safe to restart Atorvastatin treatment. Atorvastatin Tablets with fusidic acid may rarely lead to muscle weakness or pain (rhabdomyolysis). Ask your doctor or pharmacist for advice before taking any medicine.

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4. Possible side effects

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

If you experience any of the following serious side effects or symptoms, stop taking your tablets and tell your doctor immediately or go to the nearest hospital accident and emergency department. Rare: may affect up to 1 in 1,000 people:

- Serious allergic reaction which causes swelling of the face, tongue and throat that can cause difficulty in breathing.
- Swelling of the eyelids, face, lips, mouth, or throat. This can cause great difficulty in breathing.
- Rash, skin rash and itching, hives, hair loss
- Having nightmares, insomnia
- Muscle weakness, tenderness, pain.
- Joint pain, muscle pain and back pain
- Muscle breakdown (rhabdomyolysis). The coating of Atorvastatin Tablets contains colourants which can cause discoloration of urine or blood in some people.

Other possible side effects with Atorvastatin Tablets

Common side effects (may affect up to 1 in 10 people):

- Loss of memory
- Headache
- Cough
- Nasal congestion
- Pain
- Stomach pain
- Indigestion
- Nausea
- Diarrhoea
- Constipation
- Changes in taste
- Ringing in the ears and/or head
- Blurred vision
- Ringing in the ears and/or head
- Vomiting, belching, abdominal pain
- Dizziness, drowsiness, trouble falling asleep
- A sensation of weakness or tiredness
- Changing in taste
- Headache
- Skin problems
- Seizures

Uncommon side effects (may affect up to 1 in 100 people):

- Anorexia (loss of appetite), weight gain, increase in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels), increase in the liver enzyme alanine aminotransferase (ALT)
- Headache
- Nasal congestion, wind, indigestion, diarrhoea
- Joint pain, muscle pain and back pain
- Muscle breakdown (rhabdomyolysis). The coating of Atorvastatin Tablets contains colourants which can cause discoloration of urine or blood in some people.

Rare side effects (may affect up to 1 in 1,000 people):

- Unusual tiredness or weakness
- Tendon injury

Very rare side effects (may affect up to 1 in 10,000 people):

- An allergic reaction - symptoms may include swelling and redness in the eyes, swelling of the skin, face, lips, tongue or throat, difficulty breathing, collapse
- Gynecomastia (breast enlargement in men)

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

Muscle weakness is common. Possible side effects reported with some statins (medicine of the same type):

- Sexual difficulties
- Depression
- Breathing problems including persistent cough and/or shortness of breath or wheeze
- Dizziness. This is more likely if you have high levels of sugar and fat in your blood and low blood pressure. Your doctor will monitor your blood pressure while you are taking this medicine.

5. How to store Atorvastatin Tablets

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

Do not use Atorvastatin Tablets after the expiry date which is stated on the blister and on each packaging after (EAT). The expiry date refers to the last day of that month. This medicine does not need any special storage conditions other than avoiding extreme temperatures.

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.

6. Contents of the pack and other information

What Atorvastatin Film-Coated Tablets contain

The active substance is atorvastatin. Each 10 mg tablet contains 10 mg of atorvastatin (as atorvastatin calcium trihydrate).

Each 20 mg tablet contains 20 mg of atorvastatin (as atorvastatin calcium trihydrate).

Each 40 mg tablet contains 40 mg of atorvastatin (as atorvastatin calcium trihydrate).

Each 80 mg tablet contains 80 mg of atorvastatin (as atorvastatin calcium trihydrate).

What other ingredients of Atorvastatin Film-Coated Tablets are:

- Sodium lauryl sulphate, colloidal anhydrous silica, croscarmellose sodium and magnesium stearate.
- The coating of Atorvastatin Tablets contain hypromellose, microcrystalline cellulose and gelatin.

What Atorvastatin Tablets look like and contains information:

Atorvastatin Film-Coated Tablets are white oval tablets with an embossed letter A on the one side and the other side is plain.

They are marked with 10, 20, 40 or 80 on one side and the other side is plain. Each strength of Atorvastatin Tablets is supplied in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 1SU, UK.

Other formats:

To listen or to request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only). Please be ready to give the following information:

Product name Reference number Atorvastatin 10 mg Film-Coated Tablets PL 29833/0467 Atorvastatin 20 mg Film-Coated Tablets PL 29833/0468 Atorvastatin 40 mg Film-Coated Tablets PL 29833/0469 Atorvastatin 80 mg Film-Coated Tablets PL 29833/0470

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 03/2020.

These medicinal products are authorised in the Member States of the EEA under the following names:

Atorvastatin 10 mg Film-Coated Tablets, Atorvastatin 20 mg Film-Coated Tablets, Atorvastatin 40 mg Film-Coated Tablets, Atorvastatin 80 mg Film-Coated Tablets.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You may report side effects in one of the following ways (see details below) by reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or for NHSA Yellow Card in the Google Play or Apple App Store.

The UK Yellow Card Scheme website: www.hpa-pri.co.uk

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