JOSWE ATORVAST®
Atorvastatin

COMPOSITION
ATORVAST ®10, 20, 40 & 80: Each film coated tablet contains Atorvastatin Calcium (2:1), corresponding to 10 mg, 20mg, 40 mg & 80 mg Atorvastatin respectively.

INDICATIONS
***For the reduction of elevated blood lipid values**
Reduction of elevated cholesterol and triglyceride values, which do not respond adequately to other measures (such as change in diet, physical exercise, weight loss) in patients with:
- Elevated blood cholesterol values (primary hypercholesterolemia).
- Concurrently elevated cholesterol and triglyceride values in the blood (mixed hyperlipidemia).
- Genetically determined elevated blood cholesterol values in familial hyper-cholesterolemia.

CONTRAINDICATIONS
When should you not take Atorvast®?
You should not take Atorvast® if you
- Are allergic to any of its ingredients.
- Have a liver disease or if unclear and persistent elevations of hepatic function values (serum transaminases) have been found.
- Suffer from disease of the skeletal muscles.
- Are pregnant or could become pregnant.
- Are nursing.

When should you take Atorvast®?
Only after consultation with your doctor.
The following describes situations in which you should only take Atorvast® under certain conditions and with special caution. Please ask your doctor. This also applies if the information applied in the past but no longer.
Atorvastatin, the active ingredient in Atorvast® should be used with caution by patients who consume large quantities of alcohol and/ or have a history of liver disease. Please inform your doctor if you are taking any other medication (see "Interactions").
What should pregnant women and nursing mothers be aware of ?
If you are pregnant or nursing, you should not take Atorvastatin. Women of childbearing potential should only take Atorvast® if contraception is guaranteed. The safety of Atorvastatin during pregnancy and lactation has not been demonstrated.
What about children and elderly people?
Only limited experience has been obtained in the use of Atorvastatin in children.
The safety and tolerance of the recommended doses are comparable in patients older than 70 to those in younger patients.

SAFETY MEASURES FOR USE AND WARNINGS
What safety precautions should be taken?
Liver function should be tested prior to the start of therapy and then at regular intervals. If the liver function values should increase to more than triple the normal level and persist over longer periods, dose reduction or withdrawal of Atorvast® therapy is recommended.
Muscle pain (uncomplicated myalgia) has occasionally been reported in patients under Atorvastatin treatment. The increase of muscle enzymes (CPK) in the blood should be examined in patients with signs of muscle disease (myopathy). If the CPK level remains clearly elevated over a longer period, the dose should be reduced or treatment with Atorvastatin withdrawn (see "Interactions"). If muscle pain, sensitivity or weakness occurs, please inform your doctor. Clinical data have not disclosed evidence of detrimental effect of Atorvastatin on the lens of the human eye. Since, however isolated cases of lens turbidity have been observed in using related HMG-CoA-reductase inhibitor in dogs, an ophthalmological examination should be performed before starting Atorvastatin treatment and repeated once each year.
What about operating a motor vehicle or machinery, or working in an unguarded area?
There is no evidence to date that Atorvastatin has any negative effect on the reaction capacity.

INTERACTIONS
What other medications influence the effect of Atorvastatin or are influenced by Atorvastatin?
Related medications of this substance class (HMG-CoA-reductase inhibitor) have been found to interact with drugs to suppress the body's defense reactions (such as cyclosporin), with other medications to reduce elevated blood lipid values (such as fibrate, nicotinic acid derivatives), with the antibiotic erythromycin and certain drugs against fungus infections (azol-type). These interactions are experienced, among other things, as muscle pain and elevation of the muscle enzyme CPK. In rare cases, disintegration of the skeletal muscle cells (rhabdomyolysis) with renal failure has been observed. These medications and macrolide-type antibiotics should be taken at the same time with Atorvastatin only on the express instructions of your doctor (see "Safety Measures for Use and Warnings").
Taking Colestipol and Atorvastatin together results in potentiation of the lipid-reducing effect. Concurrent administration of Atorvastatin and digoxin as well as certain oral contraceptives ("the pill") results in moderate elevation of the plasma concentration of these medications. Your doctor will take this into account in determining the dose of these medications. Concurrent Administration of drugs to reduce gastric acid (antacids containing magnesium or aluminum) results in a reduction in the atorvastatin plasma concentration without any reduction in the cholesterol-reducing effect. Concurrent administration of erythromycin increases the plasma concentration of Atorvastatin. Concurrent use of Atorvastatin and warfarin, a drug to reduce viscosity of the blood, should be made under careful supervision by your doctor, especially at the start of therapy. No interaction with Atorvastatin was observed in concurrent administration of cimetidine (gastric acid inhibitor) or phenazone (pain reliever) during clinical investigations.
Please note that this information may also apply to medications taken a short while before Atorvastatin.
Diet: Concomitant intake of large quantities of grapefruit juice and atorvastatin is not recommended because grapefruit juice contains one or more components that inhibit CYP3A4 and can increase plasma concentrations of drugs metabolized by CYP3A4.

DOSING INSTRUCTIONS, ROUTE AND DURATION OF ADMINISTRATION
The following information applies, unless your doctor has prescribed differently for Atorvast®.
Please follow the instructions carefully, since Atorvast® cannot otherwise work effectively.
How much Atorvast® should you take, and how often?
Your doctor will prescribe a low-cholesterol diet before you start treatment. You should maintain this diet during therapy. The usual initial dose is 10 mg Atorvastatin once daily (= 1 filmcoated Atorvast® 10 mg tablet). Your doctor will decide on further dosing so that you will achieve the desired blood cholesterol values. A corresponding dose adjustment will be made on an individual basis at intervals of 4 or more weeks. The maximum daily dose is 80 mg Atorvastatin.
Elevated blood cholesterol values (hypercholesterolemia) or concurrent elevations of blood cholesterol and triglyceride values (mixed hyperlipidemia)
Most patients respond well to 10 mg Atorvastatin (= 1 filmcoated Atorvast® 10 mg tablet) per day. Therapeutic success becomes apparent within 2 weeks and the maximum therapeutic effect is attained usually after 4 weeks. The effect is maintained over long-term therapy.
Genetically determined elevated blood cholesterol values (familial hypercholesterolemia)
- Heterozygous familial hypercholesterolemia.
The initial dose is 10 mg Atorvastatin once daily. The dose will be individually determined by your doctor. Your doctor will prescribe dose adjustment at intervals of 4 weeks up to a daily dose of 40 mg. Then Atorvastatin may be combined with an ion exchange resin to bind bile acid, or the dose may be increased to a maximum of 80 mg Atorvastatin per day.
- Homozygous familial hypercholesterolemia
Adults: A reduction in blood cholesterol values of 18-42% was attained in most patients with a dose of 80 mg Atorvastatin per day in clinical trials. **Children:** Only limited therapeutic experience has been made with doses up to 80 mg Atorvastatin in children.
Doses for patients with limited kidney function and in elderly patients
Since kidney disease has no effect on treatment with Atorvastatin, no dose adjustment is required in patients with limited kidney function. It was found in clinical trials that no dose adjustment is required in elderly patients.
When and how should you take Atorvast®?
Atorvast® can be taken with some liquid at any time of day, independent of mealtimes.
How long should you take Atorvast®?
Atorvast® is intended for long-term use.

IMPROPER USE AND OVERDOSING
What should you do if you take too much Atorvast® (intentional or unintentional overdosing)?
No special treatment is known in case of Atorvastatin overdosing. Please inform a doctor if overdosing occurs.
What must you do if you have taken too little Atorvast®or forgotten a dose?
Do not take the double quantity, but just continue taking the usual dose.

SIDE EFFECTS
What side effects may occur when Atorvast® is used?
Atorvastatin is usually well tolerated. Side effects are usually mild and transient.
The following side effects were reported by more than 1% of patients taking Atorvastatin:
Constipation, flatulence, indigestion, stomachache, headache, nausea, muscle pain (myalgias), feeling of weakness, diarrhea and insomnia. As with other drugs of this class, increase in the liver values (transaminases) have been observed among patients treated with Atorvastatin. These changes were usually slight and transient and did not require termination of therapy.
Moreover, an increase in serum creatine phosphokinase (CPK) levels have occasionally been observed. In rare cases, this was accompanied by muscle pain, sensitivity or weakness of the musculature.
The following side effects were observed during clinical trials with Atorvastatin, but a direct relationship to the administration of Atorvastatin could not be proven in every case:
Muscle cramps, muscle inflammation (myositis), muscle disease (myopathy), tingling (paresthesia), non-inflammatory disease of the nerves (peripheral neuropathy), inflammation of the pancreas, inflammation of the liver, jaundice, loss of appetite, vomiting, loss of hair, itching, skin rash, impotence, elevated or reduced blood sugar. Chest pain, dizziness and allergic reactions have also been observed in isolated cases. If you notice any side effects, which are not listed in this text, please inform your doctor or pharmacist.
What corrective measures should be taken if side effects occur?
If you experience side effects, please tell your doctor, who will decide what steps should be taken. If liver values increase to more than triple the normal value, or elevated CPK values persist, your doctor will either reduce the dose or terminate treatment with Atorvast®.

DOSAGE FORMS AND PACKAGE CONTENTS
ATORVAST 10: 30 film coated tablets, ATORVAST 20: 10 & 30 film coated tablets, ATORVAST 40: 30 film coated tablets, ATORVAST 80: 30 film coated tablets.

- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicaments out of the reach of children.

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