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Questions and answers on Lipitor and associated names (atorvastatin, 10, 20, 40 and 80 mg tablets)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

The European Medicines Agency has completed a review of Lipitor. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that there is a need to harmonise the prescribing information for Lipitor in the European Union (EU).

What is Lipitor?

Lipitor is used together with diet to lower lipids (fats) known as cholesterol and triglycerides in the blood in patients with various types of hypercholesterolaemia (high blood cholesterol levels).

It is also used for the prevention of a first cardiovascular event (such as a heart attack) in patients considered to be at high risk.

Lipitor is also available in the EU under other trade names: Atorvastatin, Atorvastatina Nostrum, Atorvastatina Parke-Davis, Atorvastatina Pharmacia, Cardyl, Edovin, Liprimar, Orbeos, Prevencor, Sortis, Tahor, Texzor, Torvast, Totalip, Xarator and Zarator.

The company that markets these medicines is Pfizer.

Why was Lipitor reviewed?

Lipitor is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Lipitor was identified as needing harmonisation by the Co-ordination Group on the Mutual and Decentralised Procedures – Human (CMD(h)).

On 15 December 2009, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Lipitor in the EU.

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP harmonised the wording for lowering blood lipids as follows:

'Lipitor is indicated as an adjunct to diet for reduction of elevated total cholesterol (total-C), LDL-cholesterol (LDL-C), apolipoprotein B, and triglycerides in patients with primary hypercholesterolaemia including familial hypercholesterolaemia (heterozygous variant) or combined (mixed) hyperlipidaemia (corresponding to Types IIa and IIb of the Fredrickson classification) when response to diet and other nonpharmacological measures is inadequate.

Lipitor is also indicated to reduce total-C and LDL-C in patients with homozygous familial hypercholesterolaemia as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.'

The CHMP agreed on the following wording for the prevention of cardiovascular events:
'Prevention of cardiovascular events in patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors'.

4.2 Posology and method of administration

The usual starting dose is 10 mg once a day. Adjustment of dose should be made at intervals of four weeks or more. The maximum dose is 80 mg once a day.

4.3 Contra-indications

The CHMP agreed that Lipitor should not be used in patients who are hypersensitive (allergic) to atorvastatin or to any of the ingredients of the medicine. It must not be used in patients with active liver disease or unexplained persistent elevations of serum transaminases (proteins in the blood) exceeding three times the upper limit of normal. It must also not be used during pregnancy, while breast-feeding and in women of child-bearing potential not using appropriate contraception.

Other changes

The CHMP also harmonised wording for other sections of the SmPC including sections on special warnings, interaction with other medicinal products, precautions for use, pregnancy and lactation, and adverse effects.

The amended information to doctors and patients is available here.

The European Commission issued a decision on 13 December 2010.

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