22 October 2010
EMA/649010/2010
Press Office

Press release

European Medicines Agency recommends use of fibrates as second-line treatment

Benefit-risk profile of lipid-lowering medicines continues to be positive, but first-line treatment is not recommended

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of the four fibrates bezafibrate, ciprofibrate, fenofibrate and gemfibrozil continue to outweigh their risks in the treatment of patients with blood lipid disorders. However, doctors should not prescribe them to newly-diagnosed patients with blood lipid disorders as first-line treatment, except for patients with severe hypertriglyceridaemia or patients who cannot take statins.

Fibrates are a class of medicines that have been in use for many years to lower level of lipids such as triglycerides and cholesterol in the blood. They were first subject to a Europe-wide review in 2005, when the CHMP's Pharmacovigilance Working Party reviewed their benefits and risks because of limited evidence of their long-term benefits in reducing cardiovascular risks. At that time the Working Party concluded that these medicines continued to have a place in the treatment of lipid disorders but should not be used as first-line treatment.

The current review by the CHMP was initiated at the request of the United Kingdom, because a number of marketing authorisation holders of the four fibrates had questioned the conclusions of the Pharmacovigilance Working Party. The UK therefore referred the matter to the CHMP for adoption of a Europe-wide recommendation whether the existing marketing authorisations should be maintained or changed.

The Committee confirmed the conclusions of the Pharmacovigilance Working Party and recommended that fibrate-containing medicines should not be used as first-line treatment, except in patients with severe hypertriglyceridaemia and in patients who cannot use statins. For fenofibrate, the Committee noted additional new data and recommended that it can also be used together with a statin in some circumstances when a statin on its own has not been enough to completely control blood lipid levels.

The CHMP's opinion has been sent to the European Commission for the adoption of a binding decision throughout the European Union.

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Notes

1. This press release together with all relevant documents is available on the European Medicines Agency's website.
2. A question-and-answer document with more information on fibrates is available.
3. There are four fibrates available in the European Union. Bezafibrate is marketed mainly under the trade names Bezalip, Cedur, Eulitop and Befizal; ciprofibrate is marketed mainly under the trade name Lipanor; fenofibrate is marketed mainly under the trade name Lipanthyl; gemfibrozil is marketed mainly under the trade name Lopid. All of these medicines are also available as generic medicines.
4. This review was initiated under Article 31 of Directive 2001/83/EC, as amended. This type of procedure may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product, which is authorised at the level of the Member States.
5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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