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Review of metformin-containing medicines started

The European Medicines Agency (EMA) has started a review of all metformin-containing medicines. Metformin, alone or in combination with other medicines, is widely used for treating type 2 diabetes.

This review was requested by the Dutch medicines agency (the Medicines Evaluation Board, MEB) following a routine evaluation of the safety of metformin medicines. This evaluation showed that the prescribing information for metformin-containing medicines varies between countries and products in its advice on how the medicine should be used in patients with reduced kidney function.

Metformin may cause a rare but serious complication called lactic acidosis, which is when lactic acid, a natural by-product of the body, builds up in the blood faster than it can be removed. Patients on metformin who have significant reduction in kidney function are at a higher risk of developing lactic acidosis because their kidneys are unable to remove enough lactic acid. Thus, currently the prescribing information states that metformin must not be used in these patients.

The Dutch review found that the current scientific evidence might not justify contraindicating metformin in patients with moderate reduction of kidney function. This large group of patients may stand to benefit from treatment with metformin. In addition, the recommendations in the prescribing information are often inconsistent with clinical guidelines on the treatment of diabetes. Thus, the MEB considered that the prescribing information for all metformin-containing medicines should be reviewed to harmonise the recommendations on their use in patients with significant kidney problems.

EMA will now review the data on the different metformin medicines and consider how the prescribing information for these medicines should be updated, and it will issue an opinion on the marketing authorisations of these medicines across the EU.

More about the medicine

Metformin is a medicine used on its own or in combination with other medicines for the treatment of type 2 diabetes. Metformin is used together with diet and exercise to improve control of blood glucose (sugar) levels. Often metformin is combined with other diabetes medicines in the same tablet.

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Metformin-containing medicines have been authorised either centrally or through national procedures. Medicines containing metformin alone have been authorised nationally in the EU since the 1960s, but many medicines containing combinations of metformin with other diabetes medicines have been authorised centrally through EMA. For further information on these medicines, see here.

More about the procedure

The review of metformin containing medicines has been initiated at the request of the Netherlands, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's final opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.