



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommendation on use of angiotensin II receptor antagonists during pregnancy

The European Medicines Agency (EMA) has recommended that the product information of all centrally authorised angiotensin II receptor antagonists be harmonised, regarding their use during pregnancy.

Following a review of the safety of these medicines during pregnancy, the EMA's Committee for Medicinal Products for Human Use (CHMP), at its April 2008 meeting, recommended that the product information should state that the use of angiotensin II receptor antagonists should be avoided in the first three months of pregnancy.

The CHMP also confirmed that angiotensin II receptor antagonists must not be used during the second and the third trimester of pregnancy and that the contraindication already in place should therefore be maintained.

Angiotensin II receptor antagonists are used in the treatment of patients with essential hypertension (high blood pressure that has no identifiable cause).

The CHMP conclusions stem from a safety review conducted by the EMA's Pharmacovigilance Working Party. This review included also a large number of non-centrally authorised medicines. Implementation of the recommendations for non-centrally authorised medicines will follow through the appropriate national procedures.

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Notes:

1. More information is available in a [question-and-answer document](#).
2. Three angiotensin II receptor antagonists are currently available in centrally authorised medicines: irbesartan, telmisartan and valsartan.
3. Centrally authorised medicines containing Irbesartan are Aprovel, Karvea, Irbesartan BMS and Irbesartan Winthrop. Irbesartan is also available in combination with hydrochlorothiazide in the following centrally authorised medicines: Coaprovel, Karvezide, Irbesartan Hydrochlorothiazide BMS and Irbesartan Hydrochlorothiazide Winthrop.
4. Centrally authorised medicines containing telmisartan are Micardis, Pritor and Kinzalmono. Telmisartan is also available in combination with hydrochlorothiazide in the following centrally authorised medicines: MicardisPlus, PritorPlus and Kinzalkomb.
5. Valsartan is available in combination with amlodipine in the following centrally authorised medicines: Exforge, Copalia, Dafiro and Imprida.
6. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.emea.europa.eu

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