

ANNEX

**CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE
OF THE MEDICINAL PRODUCT TO BE IMPLEMENTED BY THE MEMBER STATES**

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The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

1. The Member States shall agree the details of a Patient Alert Card (PAC) with the MAH, who must provide this PAC directly to the pharmacy with each Ranexa shipment. The Pharmacist should be requested to distribute a PAC to each patient at the time Ranexa is dispensed. The PAC must include the following key messages:

Health Care Professional information

The PAC should include the following information for the healthcare professional information regarding Ranexa:

- To refer to the Ranexa SPC prior to prescribing any medications to the patient, as there are potential drug interactions which should be taken into consideration.
- Ranexa is contraindicated in patients taking:
 - Potent CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, voriconazol, posaconazol, HIV protease inhibitors, clarithromycin, telithromycin, nefazodone)
 - Class Ia (e.g. quinidine) or Class III (e.g. dofetilide, sotalol) antiarrhythmics other than Amiodarone
- A dose reduction of Ranexa may be needed in combination with:
 - Moderate CYP3A4 inhibitors (e.g. diltiazem, erythromycin, fluconazole)
 - P-gp inhibitors (e.g. ciclosporin, verapamil)
- Caution should be exercised when prescribing Ranexa to patients:
 - Taking certain other drugs mentioned in the product information
 - With certain other risk factors listed in the product information
- Inform the patient about the potential for an interaction with other prescribed medicinal products and to contact his/her doctor in case of dizziness, nausea or vomiting.

Patient information

The PAC should include the following information for the patient:

- That the card should be shown to any doctor involved in their treatment
- That prior to Ranexa treatment the patient should tell their doctor if they have any of the following:
 - Kidney problems
 - Liver problems
 - Have ever had an abnormal electrocardiogram (ECG)
 - Is taking medications to treat epilepsy, bacterial or fungal infections, HIV infection, depression or heart rhythm disorders
 - Is taking the herbal remedy St John's Wort
 - Is taking allergy medicines
- That during treatment with Ranexa the patient should:
 - Not drink Grapefruit Juice
 - Call their doctor if they feel dizzy or sick, become sick or experience any unexpected symptoms after starting Ranexa.
- To refer to the Ranexa package leaflet for more information.
- To ensure to take a list of all their other medicines with them at any visit to the health care professional.