The National Agency for Medicines and Medical Devices is reviewing the safety profile of "Diane 35"
The National Agency for Medicines and Medical Devices advises physicians to explain patients the side effects of the medicinal product

The National Agency for Medicines and Medical Devices (NAMMD) is reviewing the safety profile of "Diane 35" and advises physicians to explain patients the side effects of the medicinal product and pharmacists to release the product on prescription only.

All the side effects of Diane 35 are also included in the patient's leaflet.

On emergence of any such side effects as leg pains, swollen legs, feverishness, chest pain or difficult breathing, emergency calls on the doctor are mandatory.

At the same time, the NAMMD recommends Diane 35 be used with caution by overweight women, with a family history of thromboembolism.

The NAMMD warns pharmacists with regard to mandatory release of the product on prescription only, having regard to the need of competent medical opinion on the advisability of use of Diane 35, on a case-by-case basis.

The NAMMD closely monitors adverse reactions reported via the National Pharmacovigilance system.

So far, no lethal case associated with use of Diane 35 has been reported to the National Pharmacovigilance Centre.

On request by France, the European Medicines Agency (EMA) will now undertake a review of the Diane 35 safety profile and recommendations expressed by experts in the field following study of pharmacovigilance data available throughout the EU are to be submitted to the European Commission for issuance of a decision to be implemented in all EU Member States.

For the time being, before completion of the review, the EMA advises against discontinuation of use of Diane 3. In case of suspicions, women who use Diane 35 are advised to refer to their doctor.