

Acne pill benefits outweigh blood clot risk: EU agency

May 17 2013, by Mariette Le Roux

Europe's medicines watchdog said Friday the benefits of acne drug Diane-35, also widely used as a contraceptive, outweigh the risk of developing blood clots in the veins—when correctly prescribed.

The clot risk was "low", said a European Medicines Agency (EMA) ruling on a French-initiated review of the drug's safety.

But it stressed Diane-35 and its generics should be used only for [acne](#) treatment, as indicated by the pill's German manufacturer, Bayer.

It should only be prescribed when alternative acne treatments had failed, and measures must be taken to minimise the blood clot risk.

"These medicines should be used solely in the treatment of moderate to severe acne... in women of reproductive age," the agency said in a statement.

"Since Diane-35 and its generics are [hormonal contraceptives](#), women should not take these medicines in combination with other hormonal contraceptives"—this would expose them to high doses of the female hormone oestrogen, which has been linked to thrombosis.

Diane-35 is authorised in over 100 countries and used by millions of women.

According to the package insert on Bayer's website, Diane-35 is

indicated for hormonal skin conditions in cases that other treatments had not worked.

The leaflet seeks to discourage the drug's use for birth control alone —although Diane-35's hormone make-up means it acts as a [contraceptive](#) by blocking ovulation.

The insert does warn of a higher risk of [blood clots](#) in the blood vessels, which can break off and obstruct blood flow to key organs and cause heart attacks or strokes, even death.

In January, French health regulator ANSM suspended sales of the hormone tablet which it linked to four [thrombosis](#) deaths and more than 100 cases of blood clots in the past 25 years.

In France, Diane-35 is authorised for acne treatment but is sometimes prescribed as a contraceptive —about 315,000 women in the country used it in 2012.

In some European countries it is authorised for use as a dual acne treatment-contraception solution.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) made its ruling on Diane-35 in a sitting this week.

"Based on all available data, the PRAC concluded that Diane-35 and its generics have a place as a treatment option for certain women suffering from the above-mentioned (skin) conditions," said the statement.

But it "acknowledged that there is a need to take further measures to better address and minimise the risks of thromboembolism associated with these medicines."

The committee recommended that new warnings be developed, and said patients must be made aware of the risks, signs and symptoms of blood clots.

The PRAC's recommendation will be considered by the agency's drug authorisation coordination group, CMDh, which will take a final position within weeks.

Bayer welcomed the announcement and said it "supports our view that there is no new scientific evidence necessitating a change in the assessment of the positive benefit-risk profile of Diane-35."

The risk minimising measures mooted were in line with Bayer's own proposals to the EMA, said a company statement.

It added the CMDh's final decision will be sent to the European Commission "to take a legally binding decision throughout the EU.

"Member states will have to comply within 30 days of the commission decision."

The EMA is also reviewing so-called third- and fourth-generation birth-control pills, which do not include Diane—again at the request of France which said last year these drugs would no longer be reimbursed by the social security system for fear of blood clot risks.

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