Translated from ***Rev Prescrire*** **September 2015; 35 (383): 647-648**

gestodene + ethinylestradiol (APLEEK°)

No place for a patch containing a third-generation progestin

● **Increased thromboembolic risk and frequent patch detachment.**



NOTHING NEW

An oral oestrogen-progestin combination is the contraceptive method of choice for many women (1). Products containing a so-called third-generation progestin should be avoided, as they are associated with a higher thromboembolic risk than those containing a second-generation progestin (1).

An oestrogen-progestin combination containing *noresgeltromin* (Evra°), a third-generation progestin, is authorised in the European Union and marketed in France in the form of a transdermal delivery device (patch). Its harm-benefit balance is unfavourable (1,2). Patches containing an oestrogen plus *gestodene*, another third-generation progestin, have been authorised (Apleek°, Bayer Healthcare).

Evaluation data include two non-comparative trials in a total of 3085 women (3). During these trials, there were an average of 1 to 4 unwanted pregnancies per 1000 user-years, giving a Pearl Index of about 1 to 4 (3). In comparison, fewer than 1 pregnancy per 1000 user-years generally occurred during clinical trials of oral oestrogen-progestin combinations, but this rate rises to about 60 to 80 pregnancies per 1000 user-years in routine use (1).

About one-third of women experienced adverse effects related to the patch, mainly consisting of application site reactions and leading one-third of these women to stop using the device (3). Two women developed pulmonary embolism attributed to the contraceptive patch. Patch detachment was frequent (3).

In practice, this new transdermal device containing a third-generation progestin has an unfavourable harm-benefit balance because of an increased risk of thrombosis and frequent patch detachment. It is better to choose another contraceptive method.

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Selected references from Prescrire's literature search.



In response to our request for information, Bayer Healthcare provided us with no documentation on its product.

1- Prescrire Rédaction "Premiers Choix Prescrire. Choisir une contraception" *Rev Prescrire* 2014; **34** (368): 444-449.
2- Prescrire Editorial Staff "Thrombotic risk of contraceptive transdermal patches and the contraceptive vaginal ring" *Prescrire Int* 2013; **22** (143): 266-269.
3- HMA - CMDh "Public assessment report for Apleek. Scientific discussion" December 2014: 31 pages.

gestodene + ethinylestradiol

transdermal delivery device (patch)

APLEEK°

• **13 microg** of *ethinylestradiol* + **60 microg** of *gestodene* per 24 hours (1 patch per week for 3 weeks followed by a 7-day patch-free interval)

hormonal contraceptive; oestrogen-progestin combination

■ **Indication:** *"Female hormonal contraception".*
[EU decentralised procedure]



Editors' opinion

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Repackaging

In the food industry, repackaging involves unpacking and then repacking perishable food, such as meat, with a new use-by date. This practice is banned because of the obvious health risks linked to damaged food products. In the pharmaceutical industry, however, marketing outdated drugs is a common practice, and one that is not even prohibited.

For example, *gestodene* is a "third-generation" progestin that exposes women to a higher risk of thrombosis than a progestin such as *levonorgestrel*. Yet it has no clinical advantages. In mid-2012, because of this increased risk of thromboembolism, the French authorities declared that combined contraceptives containing *gestodene* provided "insufficient" improvement in medical treatment, and decided to stop reimbursing them. They also declared that such contraceptives should not even be considered as second-line options.

These contraceptives were therefore expected to disappear from the market. Instead, *gestodene* has emerged in a new "modernised" form (Apleek°, see above). However, delivering the *gestodene* and *ethinylestradiol* combination via fancy transparent patches in no way avoids exposing women to this higher thrombotic risk. Sticking this contraceptive to the skin rather than taking it orally changes nothing: the *gestodene* combination should still be discarded.

The pharmaceuticals market is just that, a market. Drug companies' overriding priority is to sell their products. All the more reason for the authorities to ensure that patients' interests take precedence over profits, by controlling and supervising the market more vigorously.

Gaspard

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