

Berne, November 2015

Combined hormonal contraceptives (CHC) with chlormadinone acetate or drospirenone¹ – Deletion of references relating to beneficial effects in acne (Indication/Properties) due to the increased risk of venous thromboembolism (VTE) in CHC users

Swissmedic co-ordinates the information on the above-mentioned issue in order to simplify the process, since the important notice concerns several authorisation holders: Actavis Switzerland AG, Bayer (Switzerland) AG, Berlis AG, Dermapharm AG, Effik SA, Gedeon Richter (Switzerland) AG, Mepha Pharma AG, Sandoz Pharmaceuticals AG, Spirig Healthcare AG.

Summary

- **References relating to beneficial effects in acne are deleted in the product information for CHCs with antiandrogenic properties (CHCs containing chlormadinone acetate or drospirenone). Such references have to date been included for these preparations in the sections "Indications/Uses" and "Properties/Effects". The reason for the deletion is the increased VTE risk in all CHC users compared to non-users.**
- **CHCs containing chlormadinone acetate or drospirenone are authorised for contraception and should not be used for acne.**
- **Alternative preparations that pose no increased risk of VTE are available for the treatment of acne.**

Background information

The use of all CHCs compared to non-use is associated with a higher risk of VTE. According to a review of all the scientific data conducted by the European Medicines Agency (EMA) in 2013 the VTE risk for non-users is approx. 2/10,000 woman years compared to approx. 5-12/10,000 for CHC users.

Swissmedic concludes in its own evaluation that the benefits claimed for antiandrogenic CHCs (containing chlormadinone acetate or drospirenone) except contraception do not justify their extended prescription in such indications due to the potentially life-threatening VTE risk.

CHC use in Switzerland

The VTE risk associated with CHCs is low. However, given the large number of healthy women who are prescribed CHCs, this has significant consequences: In a total of 400,000 CHC users in Switzerland (2011 estimate), the number of VTE events has been calculated at 200-480 a year according to the latest incidence figures (see above). Around 50 VTE events a year have been notified to the Swiss reporting system in the last five years, i.e. approx. 1 VTE per week (www.swissmedic.ch > Market surveillance > Human medicines > Specific topics > Hormonal contraceptives and thromboembolism).

Measures and instructions/recommendations for healthcare professionals

All references relating to beneficial effects in acne are deleted from the sections "Indications/Uses" and "Properties/Effects".

The current product information for the affected preparations will be continuously published on the Swissmedic website at www.swissmedicinfo.ch by 31 December 2015 at the latest.

CHCs containing chlormadinone acetate and drospirenone are authorised for contraception and should not be used for acne.

¹ The following CHCs containing chlormadinone acetate or drospirenone are authorised in Switzerland: Belara, Belarina, Daylette, Dretine 21, Dretine 28, Dretinelle 21, Dretinelle 28, Drospibel 20, Drospibel 20 Conti, Drospibel 30, Drospibel 30 Conti, Elenis, Eloine, Engiletta, Ladonna, Madinette, Mirjanne 20, Mirjanne 30, Queenie, Sara, Sue 20, Sue 30, Suzanne, Tyarena, Volina 20, Volina 30, Yasmin, Yasminelle, YAZ, Yira 20, Yira 30.

Reporting adverse reactions

For reports of adverse drug reactions (ADRs) Swissmedic recommends the use of the reporting portal developed for this purpose. ADRs can be recorded directly using the Electronic Vigilance System (EIViS). However, it is also still possible to use the corresponding report form and send it to the regional Pharmacovigilance Centre. This form can be found on the Swissmedic website or can be ordered directly from Swissmedic (tel. 058 462 02 23). (All the necessary information can be found at www.swissmedic.ch > Market surveillance > Pharmacovigilance).