The European Agency for the Evaluation of Medicinal Products
Post-authorisation evaluation of medicines for human use

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INFORMATION FOR WOMEN USING ORAL CONTRACEPTIVES

BACKGROUND

The European Agency for the Evaluation of Medicinal Products (EMEA) has made public the conclusions of a recent assessment on oral contraceptives which contain two hormones, one of the oestrogen type and one of the progestin type (also called "the pill").

Such combined oral contraceptives are very effective in giving an almost 100% protection against pregnancy if used properly. They have been available in Europe for more than 30 years. Their use may be associated with minor adverse reactions such as nausea, oedema, weight gain and mood changes, which are often transient. Serious adverse reactions however are rare. In fact, about 99.95% of women treated with combined oral contraceptives for one year will not experience any serious problems. Well-known serious but rare adverse reactions are venous thromboembolism, myocardial infarction and stroke.

The risk of venous thromboembolism has been under review since 1995 by the Committee for Proprietary Medicinal Products (CPMP), the scientific committee for medicines for human use of the EMEA. The review was undertaken because of newly emerging study data for specific types of oral contraceptives, namely those containing at least 20 µg (micrograms) of the oestrogen ethinylestradiol and either desogestrel or gestodene as progestin in all kind of formulations, i.e. mono-, bi- or tri-phasic formulation, (so-called "third generation" oral contraceptives).

Venous thromboembolism is the formation of blood clots in veins, mostly in the legs or in the pelvis. Its symptoms may include pain and swelling. If untreated, it can result in embolism of the lungs, a potentially life-threatening condition.

CONCLUSIONS ISSUED BY THE CPMP

- The use of any type and brand of combined oral contraceptives is associated with venous thromboembolism as a rare, but serious side effect.
- This risk is highest in the first year a woman ever uses any type of a combined oral contraceptive.
- Women using a combined oral contraceptive containing desogestrel or gestodene with 30µg of ethinylestradiol (mono-, bi- or tri-phasic formulation) have a small increased risk of venous thromboembolism compared to women using combined oral contraceptives containing levonorgestrel with less than 50 µg of ethinylestradiol.

  While in users of such levonorgestrel containing products the frequency of venous thromboembolism is estimated to be about 20 cases per 100 000 women-years of use, it is estimated to be about 30 to 40 cases per 100 000 women-years of use of desogestrel or gestodene containing products with 30 µg of ethinylestradiol.

  For oral contraceptives containing desogestrel or gestodene with 20µg of ethinylestradiol the epidemiological data do not suggest a lower risk of venous thromboembolism than for those with 30µg of ethinylestradiol.

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- However, the risk of venous thromboembolism when using any combined oral contraceptive is lower than that associated with pregnancy.

RECOMMENDATIONS TO WOMEN USING COMBINED ORAL CONTRACEPTIVES

- If you are currently using a combined oral contraceptive, there is no reason to stop taking it on the basis of these findings. If you use desogestrel or gestodene containing combined oral contraceptives, you can continue taking it, if it is well tolerated.
- If you have any questions please contact your doctor or pharmacist to obtain advice. Please obtain advice in particular if you have suspected symptoms of venous thromboembolism, such as pain and swelling in the legs or arms, or symptoms of pulmonary embolism, such as breathlessness and a sharp pain in the chest.
- Combined oral contraceptives must not be used in women with a history of or existing venous thromboembolic disease or a history of or recent myocardial infarction or stroke. Therefore, you need to inform your doctor if this applies to you.
- Risk factors your doctor will take into account when prescribing a combined oral contraceptive are severe overweight, post-partum period, i.e. the time after having given birth, recent surgical operation and family history of venous thrombosis. Please inform your doctor accordingly if this applies to you.
- If you need to undergo surgical operation, or have had a fracture, or if you are immobilised or confined to bed, please tell your doctor that you are using a combined oral contraceptive since this may have to be discontinued or treatment be started to prevent venous thromboembolism.

Further information regarding these recommendations is included in the Package Leaflet.

Further information is available on the website of the national agencies and of the EMEA (http://www.emea.eu.int).

Annex: List of website addresses:

Austria http://www.bmsg.gv.at

Belgium http://www.afigp.fgov.be

Denmark http://www.laegemiddelstyrelsen.dk

Finland http://www.nam.fi

France http://agmed.sante.gouv.fr

Germany http://www.bfarm.de

Greece http://www.ypyp.gr

Ireland http://www.imb.ie

Italy http://www.sanita.it/sanita

Luxembourg http://www.etat.lu/MS

The Netherlands http://www.cbg-meb.nl

Portugal http://www.infarmed.pt

Spain http://www.msc.es

Sweden http://www.mpa.se

United Kingdom http://www.mca.gov.uk

Iceland http://www.lyfjastofnun.is

Norway http://www.legemiddelverket.no