BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

**STEDIRIL** (ethinylestradiol 50 µg, norgestrel 500 µg), hormonal contraceptive

Insufficient actual benefit in the absence of any role in the therapeutic strategy

Main points

- STEDIRIL has Marketing Authorisation in oral hormonal contraception. Its risk of venous and arterial thromboembolism is greater than that of other 2nd generation combined oral contraceptives containing less ethinylestradiol.
- It has no role in the contraceptive strategy because of the existence of 1st and 2nd generation combined oral contraceptives containing less ethinylestradiol. It therefore does not have sufficient actual benefit to justify its reimbursement.

Contraceptive use

- The long-term contraceptive efficacy of the different types of oral oestrogen-progestogen contraceptives is of the same order.
- Before prescribing an oestrogen-progestogen contraceptive, a check must always be made for arterial or venous thromboembolic risk factors and account must be taken of the contraindications and precautions for use.
- Oral oestrogen-progestogen contraception is one of the 1st-line methods for women who have no particular risk factors (cardiovascular, oncological, hepatic, etc.). It is a very effective method when used properly. There are no data on the basis of which, in terms of contraceptive efficacy and cycle control, the prescription of a particular type of oestrogen-progestogen pill can be preferred (according to its generation or whether it is mono-, bi- or triphasic).
- All oestrogen-progestogen contraceptives are associated with an increased risk of thromboembolic accidents. However, there is an increased risk of venous thromboembolism with third-generation oral oestrogen-progestogen contraceptives by comparison with first- and second-generation oral oestrogen-progestogen contraceptives (containing less than 50 micrograms of ethinylestradiol).
- The risk of venous and arterial thromboembolism varies according to the dose of ethinylestradiol contained in oral oestrogen-progestogen contraceptives, since lower dosages of oestrogens are associated with less risk. The arterial risk increases with age: from 35 years onwards, the risk/benefit ratio of this contraception must be reassessed regularly. Between 35 and 40 years, it is recommended that oestrogen-progestogen contraception should be replaced with another form of contraception.

Role of the medicinal product in the contraceptive strategy

STEDIRIL has no role in the contraceptive strategy because of the existence of 1st and 2nd generation combined oral contraceptives containing less ethinylestradiol.

Clinical data

- Two cohort studies have shown an increased risk of arterial thrombosis: stroke (in 1 study out of 2) and myocardial infarction with the dose of ethinylestradiol contained in combined oral contraceptives. One of these studies concluded that there is a significant increase in the risk of stroke and myocardial infarction with contraceptives containing norgestrel and 50 µg ethinylestradiol by comparison with those containing levonorgestrel and 30-40 µg ethinylestradiol.

- One study (included in a meta-analysis and a systematic review) concluded that there is an increased risk of venous thromboembolism with the ethinylestradiol contained in combined oral contraceptives; the combination of levonorgestrel with 50 µg ethinylestradiol carries the greatest risk.
STEDIRIL, which contains 50 µg ethinylestradiol, is associated with a risk of venous and arterial thromboembolism greater than that associated with oestrogen-progestogens containing less than 50 µg ethinylestradiol.

Benefit of the medicinal product

- The actual benefit* of STEDIRIL is insufficient to justify reimbursement by National Health Insurance.
- Does not recommend the continuation of inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

** The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".