SUMMARY

nomegestrol acetate

LUTENYL 3.75 mg and 5 mg,

tablets (3.75 mg), film-coated tablets (5 mg)

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 12 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

In postmenopausal women: in combination with an oestrogen as a part of hormone replacement therapy (HRT)/artificial cycles (LUTENYL 3.75 mg and 5 mg (nomegestrol acetate))

- Endometrial hyperplasia increases the risk of endometrial cancer.
- This is a medicinal product for preventive treatment.
- The efficacy/adverse events ratio has not been accurately established, with the menopause considered to be the period at highest risk of developing meningioma.
- Nomegestrol acetate in combination with an oestrogen has no place in the therapeutic strategy of hormone replacement therapy in postmenopausal women.

- **Public health benefit**

Considering:

- the seriousness of the condition and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified medical need, with identification of a risk of the development of meningioma requiring the implementation of monitoring measures, including brain MRT,

a potential negative impact of LUTENYL (nomegestrol acetate) on morbidity, mortality and on quality of life is expected,
- an expected additional impact on the organisation of care,

LUTENYL (nomegestrol acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LUTENYL (nomegestrol acetate) is insufficient to justify its public funding cover in view of the available therapeutic alternatives for postmenopausal women: in combination with an oestrogen, as a part of hormone replacement therapy (HRT)/artificial cycles.

In premenopausal women: menstrual disorders related to insufficient or absent progesterone secretion, in particular menstrual cycle length abnormalities: oligomenorrhea, polymenorrhea, paniomenorrhea, amenorrhea (after aetiological assessment) (LUTENYL 5 mg (nomegestrol acetate))

- Menstrual cycle length abnormalities can significantly impair quality of life.
- This is a medicinal product for symptomatic treatment.
- The efficacy/adverse effects ratio has not been accurately established given the limited data regarding its benefit, the availability of therapeutic alternatives and the risk of development of meningioma.
- Nomegestrol acetate has no place in the management of menstrual cycle length abnormalities.

Public health benefit

Considering:
- the seriousness of the condition and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified need, and the risk of development of meningioma requiring implementation of monitoring measures including, brain MRT, a potential negative impact of LUTENYL (nomegestrol acetate) on morbidity mortality and on quality of life is expected,
- an expected additional impact on the organisation of care,

LUTENYL (nomegestrol acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LUTENYL 5 mg (nomegestrol acetate) is insufficient to justify public funding cover in women before menopause: menstrual disorders related to insufficient or absent progesterone secretion, in particular cycle length abnormalities: oligomenorrhea, polymenorrhea, spaniomenorrhea, amenorrhea (after aetiological assessment).

In premenopausal women: menstrual disorders related to insufficient or absent progesterone secretion, in particular functional gynaecological bleeding: metrorrhagia, menorrhagia, including bleedings due to fibroids (LUTENYL 5 mg (nomegestrol acetate))

- Functional haemorrhages and menorrhagia, including bleedings due to fibroids, can impair quality of life and cause anaemia.
- This is a medicinal product for symptomatic treatment.
- The efficacy/adverse effects ratio is positive (important) subject to respect for prescribing rules and for monitoring the required for meningioma risk management.
- LUTENYL 5 mg (nomegestrol acetate) is a second-line treatment when therapeutic alternatives have failed or are contraindicated, subject to compliance with the recommendations for monitoring by brain imaging. In menorrhagia due to fibroids, LUTENYL 5 mg (nomegestrol acetate) has a role as preoperative treatment only.

- **Public health benefit**

Considering:

- the seriousness of the condition and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified need, and the risk of development of meningioma requiring implementation of monitoring measures including brain, MRT, a potential negative impact of LUTENYL (nomegestrol acetate) on morbidity mortality and on quality of life is expected,
- an expected additional impact on the organisation of care,

LUTENYL (nomegestrol acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LUTENYL 5 mg (nomegestrol acetate) is substantial in premenopausal women: menstrual disorders related to insufficient or absent progesterone secretion, in particular functional gynaecological bleeding: metrorrhagia, menorrhagia, including bleedings due to fibroids(as preoperative treatment only), when the therapeutic alternatives have failed or are contraindicated, subject to compliance with the recommendations for monitoring by brain imaging (irrespective of age).

It is insufficient to justify its public funding cover in all other fibroid situations.

- **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%**

In premenopausal women: menstrual disorders related to insufficient or absent progesterone secretion, in particular functional symptoms before or during menstruation: essential dysmenorrhea, premenstrual syndrome, cyclical mastodynia (LUTENYL 5 mg (nomegestrol acetate))

- The functional symptoms before or during menstruation can impair quality of life.
- This is a medicinal product for symptomatic treatment.

- The efficacy/adverse effects ratio has not been accurately established given the limited data regarding its benefit, the availability of therapeutic alternatives and the risk of the development of meningioma, in the indication functional symptoms before or during menstruation: essential dysmenorrhea, premenstrual syndrome, non-severe cyclical mastodynia, is positive (important) only in severe cyclical mastodynia associated with mastopathy, subject to respect of prescribing rules and monitoring required for meningioma risk management.
- LUTENYL 5 mg (nomegestrol acetate) is a second-line treatment only for severe cyclical mastodynia associated with mastopathy, when therapeutic alternatives have failed or are contraindicated, and subject to compliance with the recommendations for monitoring by brain imaging. In other situations, this proprietary medicinal product has no place in the therapeutic strategy.

Public health benefit

Considering:

- the seriousness of the condition and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified need, and the risk of development of meningioma requiring the implementation of monitoring measures, MRT, a potential negative impact of LUTENYL (nomegestrol acetate) on morbidity, mortality and on quality of life is expected,
- an expected additional impact on the organisation of care,

LUTENYL (nomegestrol acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of LUTENYL 5 mg (nomegestrol acetate) is substantial only in premenopausal women : menstrual disorders related to insufficient or absent progesterone secretion, in particular functional symptoms before or during menstruation in severe cyclical mastodynia associated with mastopathy, when the therapeutic alternatives have failed or are contraindicated, subject to compliance with the recommendations for monitoring by brain imaging (irrespective of age).

It is insufficient to justify public funding cover in women before menopause: menstrual disorders due to insufficient or absent progesterone secretion, in particular functional symptoms before or during menstruation: essential dysmenorrhea, premenstrual syndrome, cyclical mastodynia other than severe cyclical mastodynia associated with mastopathy.

Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%

Clinical Added Value

Not applicable.