

SUMMARY

medrogestone

COLPRONE 5 mg

tablets

Reassessment at the request of the TC

Adopted by the Transparency Committee on 15 January 2025

Summary of opinion**Favourable opinion for reimbursement only:**

“when the therapeutic alternatives have failed or are contraindicated and in compliance with the recommendations for monitoring by brain imaging (irrespective of age) in the following indications:

- disorders related to progesterone insufficiency and particularly those observed in the premenopausal period: severe mastodynia associated with mastopathy,
- fibroid-related functional haemorrhages and menorrhagia as preoperative treatment,
- endometriosis.”

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.

Transparency Committee's conclusions**Clinical Benefit**

Disorders related to progesterone insufficiency and particularly those observed in the premenopausal period (menstrual irregularities, premenstrual syndrome, mastodynia, etc.)

- ➔ Abnormalities in cycle length can significantly impair quality of life. The functional symptoms that precede or accompany menstruation can impair quality of life.
- ➔ This is a symptomatic medicinal product.
- ➔ The efficacy/adverse effects ratio has not been adequately established given limited data concerning its benefit, the presence of therapeutic alternatives and the risk of the development of meningioma in gynaecological disorders related to progesterone insufficiency and particularly those observed in the premenopausal period (menstrual irregularities, premenstrual syndrome, mastodynia, etc.); it is high only in severe mastodynia associated with mastopathy, in accordance with the prescribing and monitoring conditions linked to the risk of meningioma.
- ➔ COLPRONE (medrogestone) only has a role as second-line treatment in severe mastodynia associated with mastopathy, when therapeutic alternatives have failed or are contraindicated, and in compliance with the recommendations for monitoring by brain imaging. In other situations, this proprietary medicinal product has no role in the care pathway.

→ Public health benefit

Considering:

- the seriousness of the disease and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified need, with identification of a risk of the development of meningioma requiring the implementation of monitoring measures, with the performance of brain imaging by MRI, a potential negative impact of COLPRONE (medrogestone) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

COLPRONE (medrogestone) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of COLPRONE 5 mg (medrogestone) is:

- **substantial only when the therapeutic alternatives have failed or are contraindicated and in compliance with the recommendations for monitoring by brain imaging (irrespective of age) in disorders related to progesterone insufficiency and particularly those observed in the premenopausal period: severe mastodynia associated with mastopathy,**
- **insufficient to justify public funding in the other MA situations.**

The Committee issues the following opinions:

- **favourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages,**
- **unfavourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in the other situations covered by the MA indication.**

→ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%

Fibroid-related functional haemorrhages and menorrhagia

- Functional haemorrhages and menorrhagia, including related to fibroids, can impair quality of life and cause anaemia.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is high provided that the prescribing and monitoring conditions related to the meningioma risk are complied with.
- Considering the identified meningioma risk, COLPRONE (medrogestone) is a second-line treatment when therapeutic alternatives have failed or are contraindicated, and in compliance with the recommendations for monitoring by brain imaging. In fibroid-related menorrhagia, COLPRONE (medrogestone) has a role as preoperative treatment only.

→ Public health benefit

Considering:

- the seriousness of the disease and its prevalence/incidence,

- the partially met medical need,
- the partial response to the identified need, with identification of a risk of the development of meningioma requiring the implementation of monitoring measures, with the performance of brain imaging by MRI, a potential negative impact of COLPRONE (medrogestone) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

COLPRONE (medrogestone) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of COLPRONE 5 mg (medrogestone) is:

- **substantial only when the therapeutic alternatives have failed or are contraindicated and in compliance with the recommendations for monitoring by brain imaging (irrespective of age) in fibroid-related functional haemorrhages and menorrhagia as preoperative treatment,**
- **insufficient to justify public funding in the other MA situations.**

The Committee issues the following opinions:

- **favourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages,**
- **unfavourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in the other situations covered by the MA indication.**

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Endometriosis

- ➔ Endometriosis-related pain can impair quality of life.
- ➔ This is a symptomatic medicinal product.
- ➔ The efficacy/adverse effects ratio is high provided that the prescribing and monitoring conditions related to the meningioma risk are complied with.
- ➔ Considering the identified meningioma risk, COLPRONE (medrogestone) is a salvage therapy when therapeutic alternatives have failed or are contraindicated, and in compliance with the recommendations for monitoring by brain imaging.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified need, with identification of a risk of the development of meningioma requiring the implementation of monitoring measures, with the performance of brain imaging by MRI, a potential negative impact of COLPRONE (medrogestone) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

COLPRONE (medrogestone) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of COLPRONE 5 mg (medrogestone) is:

- substantial only when the therapeutic alternatives have failed or are contraindicated and in compliance with the recommendations for monitoring by brain imaging (irrespective of age) in endometriosis,
- insufficient to justify public funding in the other MA situations.

The Committee issues the following opinions:

- favourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages,
- unfavourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in the other situations covered by the MA indication.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Artificial cycle in combination with an oestrogen

- ➔ Endometrial hyperplasia increases the risk of endometrial cancer.
- ➔ This is a preventive medicinal product.
- ➔ The efficacy/adverse effects ratio has not been adequately established, with the menopause being considered to be the period at highest risk of developing meningioma.
- ➔ Considering the identified meningioma risk, there is no role in the care pathway for medrogestone in combination with an oestrogen in the context of hormone replacement therapy in postmenopausal women.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence/incidence,
- the partially met medical need,
- the partial response to the identified need, with identification of a risk of the development of meningioma requiring the implementation of monitoring measures, with the performance of brain imaging by MRI, a potential negative impact of COLPRONE (medrogestone) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

COLPRONE (medrogestone) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of COLPRONE 5 mg (medrogestone) is insufficient in the MA indication.

The Committee issues an unfavourable opinion for maintenance of inclusion of COLPRONE 5 mg (medrogestone) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.