

SUMMARY

chlormadinone acetate

**CHLORMADINONE
VIATRIS 5 mg and 10 mg,
tablets**

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**

Gynaecological 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.
- ➔ It is a second-line treatment only for 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 condition 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 CHLORMADINONE VIATRIS (chlormadinone acetate) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

CHLORMADINONE VIATRIS (chlormadinone acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CHLORMADINONE VIATRIS (chlormadinone acetate) is substantial only in severe mastodynia associated with mastopathy, when the therapeutic alternatives have failed or are contraindicated and in compliance with the recommendations for monitoring by brain imaging (irrespective of age).

It is insufficient to justify public funding cover in gynaecological disorders related to progesterone insufficiency and particularly those observed in the premenopausal period (menstrual irregularities, premenstrual syndrome, mastodynia other than severe mastodynia associated with mastopathy).

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 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.
- ➔ CHLORMADINONE VIATRIS (chlormadinone acetate) 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, CHLORMADINONE VIATRIS (chlormadinone 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, 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 CHLORMADINONE VIATRIS (chlormadinone acetate) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

CHLORMADINONE VIATRIS (chlormadinone acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CHLORMADINONE VIATRIS (chlormadinone acetate) is substantial in fibroid-related functional haemorrhages and menorrhagia as preoperative treatment only, when the therapeutic alternatives have failed or are contraindicated and in 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%**

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.
- ➔ This 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 condition 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 CHLORMADINONE VIATRIS (chlormadinone acetate) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

CHLORMADINONE VIATRIS (chlormadinone acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CHLORMADINONE VIATRIS (chlormadinone acetate) is substantial in endometriosis, when the therapeutic alternatives have failed or are contraindicated and in compliance with the recommendations for monitoring by brain imaging (irrespective of age).

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 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.
- There is no role in the care pathway for chlormadinone acetate in combination with an oestrogen in the context 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 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 CHLORMADINONE VIATRIS (chlormadinone acetate) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

CHLORMADINONE VIATRIS (chlormadinone acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CHLORMADINONE VIATRIS (chlormadinone acetate) is insufficient to justify its public funding cover in view of the alternatives available in artificial cycles in combination with an oestrogen.

Dysmenorrhea

- 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 in dysmenorrhea given limited data concerning its benefit, the presence of therapeutic alternatives and the risk of the development of meningioma.
- CHLORMADINONE VIATRIS (chlormadinone acetate) has no role in the care pathway for dysmenorrhea.

→ 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, 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 CHLORMADINONE VIATRIS (chlormadinone acetate) is expected on morbidity and mortality and on quality of life,
- an expected additional impact on the organisation of care,

CHLORMADINONE VIATRIS (chlormadinone acetate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CHLORMADINONE VIATRIS (chlormadinone acetate) is insufficient to justify its public funding cover in view of the alternatives available in dysmenorrhea.

Clinical Added Value

Not applicable.