

SUMMARY

sildenafil

VIAGRA 50 mg

orodispersible film

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 23 October 2024

Summary of opinion

Favourable opinion for reimbursement only in adult men with erectile dysfunction related to one of the following conditions:

- Paraplegia and tetraplegia of any origin;
- Pelvic injuries complicated by urinary disorders;
- Sequelae of surgery (aortic aneurysm; radical prostatectomy, total cystectomy and colorectal resection) or abdominopelvic radiotherapy;
- Sequelae of priapism;
- Known diabetic neuropathy;
- Multiple sclerosis;

And those with erectile dysfunction due to long-term antipsychotic treatment.

No clinical added value compared to other medicinal products containing sildenafil.

Transparency Committee's conclusions**Clinical Benefit**

Sexuality, including erection, is a complex bio-psycho-social process. The epidemiology and aetiologies of sexual disorders are still inadequately elucidated. There are no validated criteria (let alone a threshold) to confirm that the problem reported by the patient is pathological. The same is true for the level of seriousness. However, a clear deficit or even the complete inability to have an erection can have a marked impact on quality of life.

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- ➔ VIAGRA (sildenafil) is a symptomatic treatment.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ Medicinal and non-medicinal alternatives are available.
- ➔ This is a first-line treatment in patients for whom erectile dysfunction is very probably causally related to a definite and serious physical disorder, in patients with erectile dysfunction caused by long-term antipsychotic treatment, and due to its ease of use (oral route).

➔ **Public health benefit**

VIAGRA (sildenafil) 50 mg orodispersible film is unlikely to have an additional impact on public health compared to the medicinal products containing sildenafil already available.

The Committee considers that the clinical benefit of VIAGRA (sildenafil) 50 mg orodispersible film is substantial only in adult men with erectile dysfunction related to one of the following conditions:

- Paraplegia and tetraplegia of any origin;
- Pelvic injuries complicated by urinary disorders;
- Sequelae of surgery (aortic aneurysm; radical prostatectomy, total cystectomy and colorectal resection) or abdominopelvic radiotherapy;
- Sequelae of priapism;
- Known diabetic neuropathy;
- Multiple sclerosis;
- And those with erectile dysfunction due to long-term antipsychotic treatment.

In the other situations of the MA, the clinical benefit of VIAGRA (sildenafil) 50 mg orodispersible film is insufficient to justify public funding.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use and at the MA dosages only in the situations specified above. In other situations, it issues an unfavourable opinion for funding.

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

Clinical Added Value

These medicinal products are a range supplement that do not provide any clinical added value (CAV V) compared to the forms already listed.