HAUTE AUTORITÉ DE SANTÉ

GYNAECOLOGY
Update
January 2018

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

POLYGYNAX and POLYGYNAX VIRGO (neomycin, polymyxin B, nystatin), **TERGYNAN** (neomycin, metronidazole, nystatin), antiinfectives and antiseptics for gynaecological use

Low clinical benefit in the local treatment of vaginitis caused by sensitive bacteria and non-specific vaginitis

Main points

- POLYGYNAX, POLYGYNAX VIRGO and TERGYNAN have Marketing Authorisation in the local treatment of vaginitis caused by sensitive bacteria and non-specific vaginitis.
- A randomised double-blind trial found no significant difference between POLYGYNAX and miconazole administered by vaginal route(GYNO DAKTARIN) in terms of efficacy in the empirical treatment of infectious vaginitis
- For TERGYNAN, no new clinical data have been supplied by the company.

Therapeutic use

- Two aetiologies are relevant to POLYGYNAX, POLYGYNAX VIRGO and TERGYNAN: bacterial vaginosis (or “non-specific vaginitis”) and candidosis.
  The first-line treatment for bacterial vaginosis is metronidazole administered by oral route (500 mg x 2/day) or by vaginal route for 7 days.
  The first-line treatments for vulvovaginal candidosis are azole antifungal agents administered by vaginal route for 1 to 7 or 14 days, depending on the products.
- Aside from these two non-sexually transmitted infections mentioned in all recommendations for vaginitis (bacterial vaginosis and mycosis), POLYGYNAX, POLYGYNAX VIRGO and TERGYNAN can be used for the treatment of vaginitis caused by common bacteria.
- **Role of the medicinal product in the therapeutic strategy**
  POLYGYNAX, POLYGYNAX VIRGO and TERGYNAN are adjuvant treatments for vaginitis.

Clinical data

- In a controlled, randomised, double-blind trial (PRISM), the clinical efficacy of POLYGYNAX was compared to miconazole administered by vaginal route (GYNO DAKTARIN) in empirical treatment of infectious vaginitis in women with abnormal leucorrhoea associated with at least one functional complaint suggestive of a bacterial, non-specific or mixed vaginitis (suprainfected fungal vaginitis).
  The percentage of clinical success at the end of the treatment (clinical exam by the investigator on D15, primary endpoint) was 91.1% in the POLYGYNAX group (n=326) and 86.7% in the GYNO DAKTARIN group (n=332). No statistically significant difference was found between the two groups.
- The most common adverse event under treatment with POLYGYNAX was headache.
- Two published studies of low level of evidence have concluded that the treatment was clinically successful in 76.6% and 97.8% of cases, respectively.

Benefit of the medicinal product

- The actual benefit* of POLYGYNAX, POLYGYNAX VIRGO and TERGYNAN is low
- Recommends continued inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 10 January 2018 (CT-13070, CT 15653 and CT14767)

* 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”.