

# Secnidazole 2 mg

sachet 



## First oral single-dose treatment for bacterial vaginosis

### Key features

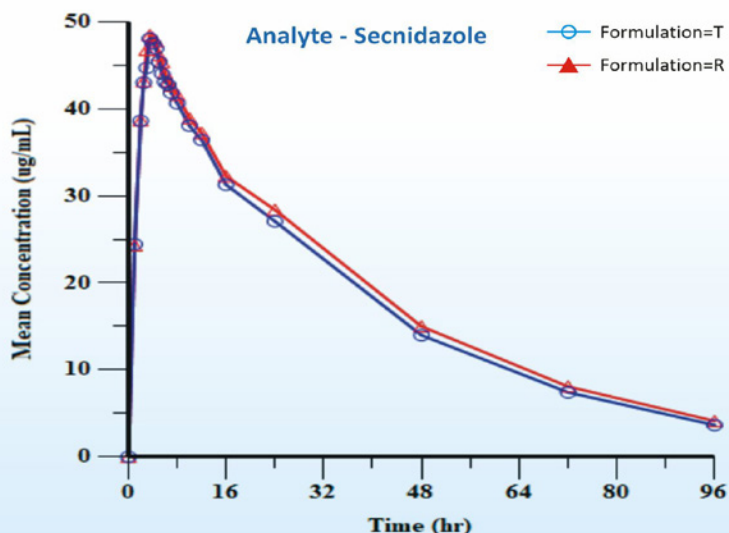
- Single-dose oral treatment of bacterial vaginosis vs. oral metronidazole twice a day for seven days, or tinidazole or clindamycin for two to seven days<sup>1</sup>.
- No significant drug-drug interaction with oral contraceptives containing ethinyl oestradiol & norethindrone<sup>2</sup>.
- Administration can occur without regard to the timing of meals.

### Competitive advantages

- Next-generation 5-nitroimidazole prodrug granted priority review by the FDA with longer half-life (17h) allowing for a once-daily dosing.
- Secnidazole has similar activity against the range of microorganisms associated with bacterial vaginosis compared to metronidazole or tinidazole whilst sparing Lactobacilli, beneficial microorganisms<sup>3</sup>.

### Regulatory status

- INN: Secnidazole
- ATC Code: P01AB07
- CAS registry number: 3366-95-8
- Reference compound: SECNOL<sup>®</sup>, Iprad.
- BioEq. study
  - Patient population: 30 male & female healthy volunteers.
  - Methodology: Randomized 2-way crossover single dose study.
  - Reference product: SECNOL<sup>®</sup> 2 g sachet Iprad, France.
- Zone IV stability data available.
- CTD dossier available.



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GYNAECOLOGY

## Information at a glance

- Commercial batch size (thousand doses): 65
- Dossier Batch size (thousand doses): 65
- Shelf-life: 2 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Pellets is self-sealed polyethylene bag and finished pack in paper alu. coated sachet
- Sachet weight / strength: 4 228 mg

## Market highlights

- 84% of women suffering from bacterial vaginosis have no symptoms (CDC).
- Prevalence of bacterial vaginosis is estimated to be 29,2% in women aged 14-49 (21.1M) (CDC).
- Global Bacterial Vaginosis Drug market is valued at \$800 million in 2018 and will reach \$1.03 billion by 2025 (CAGR 2019-25: 3.2%)<sup>4</sup>.

## Competitors' landscape

- FLAGYL®/Metronidazole, members of the 5-nitroimidazole class (FASIGYN®/tinidazole, XYNOR®/ornidazole), CLEOCIN®/clindamycin.

### REFERENCES

1. Elliott W et al *Reliasmedia Pharmacology update* (2017)
2. Center for Disease Control and Prevention *Sexually Transmitted Diseases Treatment Guideline* (2015)
3. Petrina MAB et al *Anaerobe* [internet] Elsevier Ltd 47:115-9 (2017)
4. *Global Bacterial Vaginosis Drug Market 2020 360Market updates* (2020)



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## Key numbers

- Global Bacterial Vaginosis valued \$1.06 billion by 2025
- CAGR of 1.1% between 2020-2025

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