

# FEMOLENE

VAGINAL SPRAY

**SCHEDULING STATUS:**

Not scheduled

**PROPRIETARY NAME (AND DOSAGE FORM):**

FEMOLENE VAGINAL Spray

**COMPOSITION:**

<b>Each ml contains 300 million CFU (colony forming units) of:</b>
<i>Lactobacillus gasseri</i>
<i>Lactobacillus acidophilus</i>
<i>Lactobacillus rhamnosus</i>

**PHARMACOLOGICAL CLASSIFICATION:**

Health Supplement. D. 32.16 Other.

**DISCIPLINE OF MEDICINE:**

Probiotic vaginal spray.

**PHARMACOLOGICAL ACTION:**

The human vagina is colonised by more than 50 species of probiotic bacteria of which lactobacilli are the most common. These colonies of bacteria are subject to compositional change for a variety of reasons, predisposing the person to yeast infections, bacterial vaginosis and urinary tract infections. The overgrowth of pathogenic gram negative and positive anaerobes and cocci, and the depletion of lactobacilli are typical in these conditions.

The main aim of this spray-based product is to re-introduce viable colonies of peroxide producing, Lactobacilli probiotic bacteria that are normally found in the human vagina. The recovery of the vaginal microflora may alleviate the symptoms and disease progression of vaginal yeast infections, bacterial vaginosis and urinary tract infections. The mechanism of action involves the disruption of yeast biofilms, suppression of pathogenic gram positive and negative bacteria and the inhibition of urogenital pathogens. This intervention may improve cure rate and limit recurrence of infections. The spray can be used in conjunction with oral antibiotic and antifungal therapies.

**INDICATIONS:**

Vaginal dryness, vaginal thrush, urinary tract infections (UTI), bacterial vaginosis.

**CONTRA-INDICATIONS:**

FEMOLENE VAGINAL Spray is contra-indicated in individuals who are hypersensitive to any of the ingredients.

**PREGNANCY AND LACTATION:**

Reduce the risk of bacterial vaginosis during pregnancy.

**DOSAGE AND DIRECTIONS FOR USE:**

For overall vaginal health and hygiene spray twice daily.

For vaginal thrush, bacterial vaginosis or UTI – use 3-4 times daily.

Use liberally before sexual intercourse on both participants.

**SHAKE WELL BEFORE USE.****IDENTIFICATION:**

An oily liquid with suspended material having an acidic smell.

**PRESENTATION:**

A 25 ml amber glass bottle with a metered spray insert, containing approximately 80 sprays respectively.

**STORAGE INSTRUCTIONS:**

Store in a cool, dry place below 25 °C.

**KEEP OUT OF REACH OF CHILDREN.****REGISTRATION NUMBER:**

Will be allocated by the Council upon registration.

**NAME AND BUSINESS ADDRESS OF APPLICANT:**

KENZA HEALTH (Pty) Ltd 51 APD Office Park, Kelvin Street, Kya Sands

Customer Care: 0860 103 359

www.femolene.co.za

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

June 2017

**DISCLAIMER:**

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

# FEMOLENE

## VAGINAL SPRAY

**SKEDULE STATUS:**

Nie geskeduleer

**BESIGHEIDS NAAM (EN DOSIS VORM):**

FEMOLENE VAGINAL Spray

**SAMESTELLING:**

<b>Elke ml bevat 300 miljoen CFU (kolonie vorm eenhede) van:</b>
<i>Lactobacillus gasseri</i>
<i>Lactobacillus acidophilus</i>
<i>Lactobacillus rhamnosus</i>

**FARMAKOLOGIESE KLASSIFIKASIE:**

Gesondheids Aanvulling, D.32.16 Ander.

**DISSCIPLINE VAN MEDISYNE:**

Probiotiese vaginale sproei.

**FARMAKOLOGIESE AKSIES:**

Die menslike vagina word gekoloniseer deur meer as 50 spesies probiotiese bakterieë waarvan die lactobacilli groep die mees prominent is. Hierdie bakteriële kolonies is egter onderworpe aan veranderinge in komposisie wat die mens meer vatbaar maak vir gis infeksies, bakteriële vaginose en urienweg infeksies. Die oorgroei van gram negatiewe en positiewe bakteriële patogene is tipies in hierdie toestande en dit gaan beduidend gepaard met die uitputting van die probiotiese Lactobacilli.

Die hoofdoel van hierdie sproei gebaseerde produk is om lewensvatbare kolonies van peroksied produserende lactobacilli weer terug te plaas in die vagina. Die herstel van die vaginale mikroflora mag help met die simptome en eventuele herstel van vaginale gis infeksies, bakteriële vaginose en urienweg infeksies. Die meganismes van aksie behels die disruptie van gis mikrofilm, onderdrukking van patogene bakteriële proliferasie en die inhibisie van urogenitale patogene. Die intervensie kan 'n belangrike rol speel in suksesvolle herstel van hierdie toestande en die beperking van herinfeksie. Die sproei kan gebruik word in samewerking met orale antibiotiese en antifungale terapieë.

**INDIKASIES:**

Wanneer daar 'n vel wanbalans is, soos brandboutjies en kandidiasis (sproei), help FEMOLENE VAGINAL Spray om die vel mikroflora te herstel en in stand te hou.

**KONTRA-INDIKASIES:**

FEMOLENE VAGINAL Spray het kontra indikasies vir persone wat hipersensitief is vir enige van die bestanddele.

**DOSIS EN GEBRUIKSAANWYSINGS:**

Vir algehele vaginale gesondheid en higiëne spuit twee keer per dag.

Vir vaginale sproei, bakteriële vaginosis of UTI - gebruik 3-4 keer per dag.

Gebruik mildelik voor seksuele omgang op beide deelnemers.

**SKUD GOED VOOR GEBRUIK.****IDENTIFIKASIE:**

'n Olierige vloeistof met opgeskorte materiaal met 'n suur reuk.

**AANBIEDING:**

'n 25 ml bruin bottel met 'n spuit meter insetsel, en bevat ongeveer 80 spuite onderskeidelik. FEMOLENE VAGINAL Spray hoef nie in die yskas gehou te word nie.

**SWANGERSKAP EN BORSVOEDING:**

Verminder die risiko van bakteriële vaginose tydens swangerskap

**BERGINGS INSTRUKSIES:**

Bewaar in 'n koel, droë plek teen of benede 25 °C.

**HOU BUIE BEREIK VAN KINDERS.****REGISTRASIENOMMER:**

Sal toegeken word met registrasies deur Raad.

**NAAM EN BESIGHEIDS ADRES:**

KENZA HEALTH (Pty) Ltd 51 APD Office Park, Kelvin Street, Kya Sands

Customer Care: 0860 103 359

www.femolene.co.za

**DATUM VAN PUBLIKASIE VAN VOUBILJET:**

Junie 2017

**VRYWARING:**

Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of voorkom nie.