VI.2 - Elements for a Public Summary (Gynecological)

VI.2.1 - Overview of disease epidemiology

Vulvovaginal candidiasis is caused by an overgrowth of *Candida albicans* in 90% of women. An estimated 75% of women will experience at least one episode during their lifetime. Ten to twenty percent of women are asymptomatic vaginal carriers; this may be up to 40% during pregnancy.
Other causes of vaginal discharge may be bacterial vaginosis (the most common cause of abnormal vaginal discharge in woman of childbearing age) and *Trichomonas Vaginalis* (a flagellated protozoan, almost exclusively sexually transmitted). Mixed infections may occur.

VI.2.2 - Summary of treatment benefits

According to therapeutic guidelines (*Sherrard J, Donders G, White D, Jensen JS. European (IUSTI/WHO) guideline on the management of vaginal discharge. International Journal of STD & AIDS 2011; 22: 421–429)* topical azoles are the recommended treatment for patients with vulvovaginal candidiasis. Treatment with azoles results in relief of symptoms and negative cultures among 80–90% of patients after treatment is completed, whether administered orally or topically.

The vaginal application of fenticonazole is highly effective in producing both symptomatic relief and mycological sterilization in patients with vulvovaginal candidiasis. The efficacy of fenticonazole in patients with vulvovaginal candidiasis has been demonstrated in placebo and in active controlled clinical studies vs other azoles (including clotrimazole and fluconazole). It has also been confirmed in open label studies conducted in patients with vulvovaginitis due to Candida with or without superinfections due to Gram + bacteria.
Fenticonazole 1000 mg ovule is also effective in patients with *Trichomonas vaginalis*, but a systemic treatment per oral route is the treatment of choice in such cases, if not otherwise contraindicated.

VI.2.3 - Unknowns relating to treatment benefits

Fenticonaziole has a wide post-marketing experience and no safety concern is associated with unknowns relating to treatment benefits.

VI.2.4 - Summary of safety concerns

Important identified risks

None

Important potential risks

Risk	What is known	Preventability
Use in pregnancy and lactation	There are limited amount of data from the use of fenticonazole in pregnant women. No data are available during lactation.	Fenticonazole should be used in pregnancy and lactation under the supervision of a physician.

Risk	What is known	Preventability
	Studies in animals have shown no teratogenic effects, but embriotoxic and fetotoxic effects have been observed at very high doses administered orally. Animal studies via the oral route have shown that fenticonazole and/or its metabolites can be excreted in the milk. . . Low systemic exposure of fenticonazole is expected following vaginal treatment.	During pregnancy the applicator should not be used.

Missing information

None.

VI.2.5 - Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 - Planned post authorisation development plan

No post-authorization clinical study has been required to address a specific safety concern or efficacy issue.

VI.2.7 - Summary of changes to the Risk Management Plan over time

Version	Date	Safety concern	Comment
1	July 2015	Important potential risk: Use in pregnancy and lactation	Version 1 has been assessed during DCP No. DK/H/2567/001-003/DC
2	March 2016	No change	Two separate sections have been prepared for Section IV.2 Elements for a public summary: one for gynecological and the other for dermatological indications.

VI.2 - Elements for a Public Summary (Dermatological)

VI.2.1 - Overview of disease epidemiology

Superficial fungal infections of the skin are common in patients of all ages and include a large portion of all the dermatological disorders seen by primary care physicians. There are different types of superficial fungal infection of the skin, including dermatophytoses, candidiasis and pityriasis versicolor:

- Dermatophytoses (called “tinea”) are fungal infections of keratin in the skin sustained by dermatophytes belonging to the genera *Epidermophyton, Microsporum and Trichophyton*. Common dermatophytoses include tinea barbae, tinea capitis, tinea corporis, tinea cruris and tinea pedis.
- Candidiasis is a fungal infection caused by yeasts from the genus Candida. Skin candidiasis can affect different locations, including intertrigo, perleche, facial candidiasis, “diaper” candidiasis, perineal and scrotal candidiasis.
- Pityriasis versicolor is a superficial infection of the stratum corneum of the epidermis by the yeast *Malassezia furfur*. Its name is due to the fact that the infection produces areas of diversified pigmentation of the stratum corneum.

VI.2.2 - Summary of treatment benefits

Topical therapy is recommended for a localized tinea infection because dermatophytes rarely invade living tissues and topical azoles show high rates of clinical efficacy. Most localized cutaneous candidiasis infections may also be treated with topical antifungal agents. Tinea versicolor can also be successfully treated with various agents, including azoles.

Fenticonazole is an imidazole antimycotic agent that has been shown to be effective against dermatophytes, *Candida Spp*. and *Malassezia furfur* both *in vitro* and *in vivo*. The results of the clinical trials in superficial fungal infections of the skin show that fenticonazole is a safe and effective antifungal agent for the treatment of dermatophytoses, Pityriasis versicolor and candidiasis, which is be applied once or twice daily for periods ranging from 1 to 8 weeks, according to response.

VI.2.3 - Unknowns relating to treatment benefits

Fenticonaziole has a wide post-marketing experience and no safety concern is associated with unknowns relating to treatment benefits.

VI.2.4 - Summary of safety concerns

Important identified risks

None

Important potential risks

Risk	What is known	Preventability
Use in pregnancy and lactation	There are limited amount of data from the use of fenticonazole in pregnant women. No data are available during lactation.	Fenticonazole should be used in pregnancy and lactation under the supervision of a physician.

Risk	What is known	Preventability
	Studies in animals have shown no teratogenic effects, but embriotoxic and fetotoxic effects have been observed at very high doses administered orally. Animal studies via the oral route have shown that fenticonazole and/or its metabolites can be excreted in the milk. . . Low systemic exposure of fenticonazole is expected following vaginal treatment.	During pregnancy the applicator should not be used.

Missing information

None.

VI.2.5 - Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 - Planned post authorisation development plan

No post-authorization clinical study has been required to address a specific safety concern or efficacy issue.

VI.2.7 - Summary of changes to the Risk Management Plan over time

Version	Date	Safety concern	Comment
1	July 2015	Important potential risk: Use in pregnancy and lactation	Version 1 has been assessed during DCP No. DK/H/2567/001-003/DC
2	March 2016	No change	Two separate sections have been prepared for Section IV.2 Elements for a public summary: one for gynecological and the other for dermatological indications.