VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Fungal *Candida* species are commonly found in the gastrointestinal tract, mouth , and genital areas as harmless commensals and colonize the skin and mucosal surfaces of humans. Critically ill or otherwise immunocompromised patients are more prone to develop both superficial and life-threatening *Candida* infections. Asymptomatic oral carriage of *Candida* spp. occurs in about 24-70% of children and adults with a reduced frequency in babies less than 1 year of age among healthy individuals. *C. albicans* represents the majority (38-76%) of isolates identified in both adults and children. The frequency of *C. albicans* varies across different age groups with far greater proportions of isolates identified as *C. albicans* occurring in young babies and the elderly. Although *C. albicans* is the most prevalent species involved in invasive fungal infections, the incidence of infections due to non-albicans species is increasing. Changes in the epidemiology have also been observed in Latin American countries. In European countries, an analysis showed that more than half of cases of candidaemia were caused by *C. albicans* and incidence rates for non-albicans candidaemia infections were 14% each for *C. glabrata* and *C. parapsilosis*, 7% for *C. tropicalis* and 2% for *C. krusei*. **[Khaled H. A et al. 2012; Sardi J. C. O. et al. 2013]**

VI.2.2 Summary of treatment benefits

Oral nystatin is not absorbed to any measure by the body but acts locally in the mucosa and reduces fungal colonisation of the gastrointestinal tract. It is administered for fungal infections in the mouth and intestines. Nystatin antifungal therapy can also be used in the children and infants and it provides a better efficacy and safety profile in children and infants. **[PIL of Nystimex 100000 IU/ml oral suspension; CTD module 2.5]**

VI.2.3 Unknowns relating to treatment benefits

It is unknown whether nystatin may cause birth defects. It is not known whether nystatin affects reproduction. Effects of nystatin on the pregnant women are also unknown. It should be prescribed to the pregnant woman if the potential benefits overweigh the potential risks. It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is prescribed to a nursing woman.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergic reactions (Hypersensitivity reactions, including anaphylactic reactions)	Hypersensitivity reactions and local skin swelling mayoccur, a reaction in which the face and neck may swell considerably	Yes, if irritation or hypersensitivity reactions occur, treatment should be discontinued to the patients. If patients get any of these side effects, they should directly inform their doctor.
Serious skin reactions as Steven Johnson syndrome	Serious skin and mucosal changes (so called Stevens-Johnson syndrome) may occur upon use of nystatin	Yes, Nystatin treatment should be discontinued to the patients in case of severe skin reactions. If patients get any of these side effects, they should directly inform their doctor.

Important potential risks:
None

Missing information:

Risk	What is known
Use in pregnant women	It is not known whether nystatin can cause birth defects. Effects of nystatin in pregnant women are not known. Nystatin should only be prescribed to a pregnant woman if the potential benefits overweigh the potential risks.

Risk	What is known
Use in breast-feeding mothers (Use in lactating mothers)	It is unknown whether nystatin passes into breast milk. Precaution should be taken when nystatin is prescribed to a nursing woman.

VI.2.5 Summary of risk minimization measures by safety concern

Summary of Product Characteristics (SmPC) of Nystimex 100000 IU/ml oral suspension 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). All these

risk minimization measures are given in SmPC and PL of Nystatin Sugarfree 100000 IU/ml oral suspension.

This medicine has no additional risk minimization measures.

VI.2.6 Planned post authorisation development plan

No post authorisation study is planned for this product.

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

This section is not applicable as this is version 01 of RMP.