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.

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 colonization of the gastrointestinal tract. It is administered for fungal infections in the mouth and intestines. Nystatin antifungal therapy can also be used in children and infants and it provides a better efficacy and safety profile in children and infants.

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 severe allergic (anaphylactic) reactions	Hypersensitivity reactions including swelling of the face and neck (angioedema) may occur.	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 reaction “Steven Johnson syndrome”	Serious skin changes, so called Stevens-Johnson syndrome, may occur upon use of nystatin	Nystatin treatment should be discontinued to the patients in case of severe skin reaction. If patients get the side effect, they should directly inform their doctor.

Important potential risks
None

Missing information

Risk	What is known
Use during pregnancy	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.
Use during breast-feeding (lactation)	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 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.

The Summary of Product Characteristics and the Package leaflet for Nystatin Orifarm can be found at the homepage of the National Health Authority.

This medicine has no additional risk minimisation 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

Not applicable as this is the initial risk management plan.