PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF THE RISK MANAGEMENT PLAN FOR: Lomexin (brand name taken as reference in the DCP), Falvin, Fenizolan, Fenizolan Kombi, Gynoxin, Laurimic, Lorenil, Terlomexin (Gynecological fenticonazole)

This is a summary of the risk management plan (RMP) for Lomexin. The RMP details important risks of Lomexin, how these risks can be minimised and how more information will be obtained about Lomexin's risks and uncertainties (missing information).

Lomexin's Summary of product characteristics (SmPC) and its package leaflets give essential information to healthcare professionals and patients on how Lomexin should be used.

Important new concerns or changes to the current ones will be included in updates of Lomexin's RMP.

I. The medicine and what it is used for

Lomexin is authorised for the treatment of vulvovaginal candidiasis (all countries) and mixed infections (in some countries). It contains fenticonazole nitrate as the active substance and it is given by vaginal route only as 20 mg/g vaginal cream, 200 mg vaginal capsule, 600 mg vaginal capsule, 1000 mg vaginal capsule and 0.2% vaginal solution.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Lomexin, together with measures to minimise such risks and the proposed studies for learning more about Lomexin's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Lomexin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Lomexin. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	Use in pregnancy and lactation
Missing information	None

II.B Summary of important risks

Important potential risk: Use in pregnancy and lactation	
Evidence for linking the risk to the medicine	Cumulative post-marketing experience up to DLP 27 Sep 2020.
Risk factors and risk groups	Women of childbearing potential.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 4.6 PL section 2 Additional risk minimisation measures: None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Lomexin.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Lomexin.

SUMMARY OF THE RISK MANAGEMENT PLAN FOR: Falvin, Fenizolan, Laurimic, Lomexin, Lorenil, Falvin (Dermatological fenticonazole)

This is a summary of the risk management plan (RMP) for Dermatological fenticonazole. The RMP details important risks of Dermatological fenticonazole, how these risks can be minimised and how more information will be obtained about Dermatological fenticonazole risks and uncertainties (missing information).

Dermatological fenticonazole Summary of product characteristics (SmPC) and its package leaflets give essential information to healthcare professionals and patients on how Dermatological fenticonazole should be used.

Important new concerns or changes to the current ones will be included in updates of Dermatological fenticonazole RMP.

I. The medicine and what it is used for

Dermatological fenticonazole is authorised for:

- Dermatomycoses from dermatophytes (Tricophyton, Microsporum, Epidermophyton) in different locations: tinea capitis, tinea corporis, tinea cruris, tinea pedis (athletes foot), tinea manuum, tinea faciei, tinea barbae, tinea unguium.

- Skin candidiasis (intertrigo, perleche, facial candidiasis, “diaper” candidiasis, perineal and scrotal candidiasis); balanitis, balanoposthitis; onychia and paronychia.

- Pityriasis versicolor (from Pityrosporum orbiculare and P. ovale).

- Otomycosis (from Candida or yeasts); only if there are no ear drum lesions.

- Erythrasma

- Mycosis with bacterial superinfections (from Gram-positive bacteria).

- Treatment of infections of the scalp from the yeast Pityrosporum such as seborrheal dermatitis and Pityriasis capitis.

20 mg/g cream and gel - is indicated for the treatment of glabrous skin, of skin folds and mucosa. Preferably, it is used for dry mycosis: pityriasis versicolor, erythrasma, onychomycosis; the cream is suitable for use in male genital mycosis.

20 mg/ml cutaneous spray, solution, cutaneous solution and shampoo – they are indicated for use on the scalp and skin areas covered by hair. The spray solution is, moreover, easy and convenient to use for extensive mycosis and for areas which are difficult to reach.

20 mg/g cutaneous powder - it is used for athletes foot and, in general, for the intertrigous areas and for humid lesions, both as single treatments and in addition to the cream.

It contains fenticonazole nitrate as the active substance and it is given by external topical route only as 20 mg/g cream, 20 mg/mg gel, 20 mg/ml cutaneous solution, 20 mg/ml cutaneous spray, solution, 20 mg/g cutaneous powder and 20 mg/ml shampoo.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Dermatological fenticonazole, together with measures to minimise such risks and the proposed studies for learning more about Dermatological fenticonazole risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Dermatological fenticonazole are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Dermatological fenticonazole. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	Use in pregnancy and lactation
Missing information	None

II.B Summary of important risks

Important potential risk: Use in pregnancy and lactation	
Evidence for linking the risk to the medicine	Cumulative post-marketing experience up to DLP 27 Sep 2020.
Risk factors and risk groups	Women of childbearing potential.
Risk minimisation measures	Routine risk minimisation measures:

	SmPC sections 4.4 and 4.6 PL section 2 Additional risk minimisation measures: None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Dermatological fenticonazole.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Dermatological fenticonazole.