

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Active substance (INN or common name):	clindamycin phosphate
Pharmaco-therapeutic group (ATC Code):	Lincosamide antibiotic (J01FF01)
Name of Marketing Authorisation Holder or Applicant:	Pharmacia Limited Ramsgate Road Sandwich Kent CT13 9NJ
Number of medicinal products to which this RMP refers:	<ul style="list-style-type: none">• 1
Product(s) concerned (brand name(s)):	Cleocin Dalacin Dalacin V

Data lock point for current RMP

31 July 2013

Version number

1.1

Date of final sign off

30 April 2014

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6.1. ELEMENTS FOR SUMMARY TABLES IN THE EPAR

6.1.1. Summary Table of Safety Concerns for Clindamycin Ovules

Summary of Safety Concerns	
Important identified risks	Vulvovaginal candidiasis Pseudomembranous colitis
Important potential risks	Weakening of latex condoms and diaphragms
Missing information	Use in elderly patients over 65 years of age Use in pregnant and lactating women Use in pediatric patients under 16 years of age Use in immunodeficient patients Use in patients with colitis

6.1.2. Table of On-going and Planned Studies in the Post-authorisation Pharmacovigilance Development Plan

There are no ongoing or planned studies.

6.1.3. Summary of Post-Authorisation Efficacy Development Plan

There are no ongoing or planned studies.

6.1.4. Summary Table of Risk Minimisation Measures

Safety Concern	Routine Risk Minimisation Measures	Additional Risk Minimization Measures
Important Identified Risk		
Vulvovaginal candidiasis	<u>Summary of Product Characteristics (SmPC)</u> 4.4 Special warnings and precautions for use 4.8 Undesirable effects	None
Pseudomembranous colitis	<u>SmPC</u> 4.3 Contraindications 4.4 Special warnings and precautions for use	None
Important Potential Risks		
Weakening of latex condoms and diaphragms	<u>SmPC</u> 4.4 Special warnings and precautions for use 6.2 Incompatibilities	None

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Missing Information		
Use in elderly patients over 65 years of age	<u>SmPC</u> 4.2 Posology and method of administration	None
Use in pregnant and lactating women	<u>SmPC</u> 4.4 Special warnings and precautions for use 4.6 Pregnancy and lactation	None
Use in pediatric patients under 16 years of age	<u>SmPC</u> 4.2 Posology and method of administration 4.4 Special warnings and precautions for use	None
Use in immunodeficient patients	<u>SmPC</u> 4.4 Special warnings and precautions for use	None
Use in patients with colitis	<u>SmPC</u> 4.4 Special warnings and precautions for use	None

6.2. ELEMENTS FOR A PUBLIC SUMMARY

6.2.1. Overview of Disease Epidemiology

Bacterial vaginosis is the most common vaginal infection in women of childbearing age. It occurs when the normal bacterial balance in the vagina becomes disrupted, causing an overgrowth of certain “bad” types of bacteria and infection. This can result in symptoms such as bad odor, itching, burning, increase in vaginal discharge (fluid coming out of the vagina) or pain after intercourse. However, most women do not show any symptoms at all. Since the symptoms described can also be caused by other conditions, patients must always inform their doctor of their situation.

6.2.2. Summary of Treatment Benefits

Clindamycin phosphate vaginal ovules are pessaries for use in the vagina. They contain clindamycin phosphate, which is an antibiotic used in the treatment of a bacterial infection of the vagina called bacterial vaginosis.

These antibiotics work by stopping bacterial growth. The treatment should be completed as prescribed by a healthcare professional.

6.2.3. Unknowns Relating to Treatment Benefits

None.

6.2.4. Summary of Safety Concerns

Important Identified Risk

Risk	What is Known	Preventability
Fungal (yeast) infection; inflammation of the vagina (Vulvovaginal candidiasis)	Vaginal yeast infection is characterized by vaginal itching, soreness, and irritation; pain or discomfort during sexual intercourse; pain or discomfort during urination; and vaginal discharge. It is caused by an overgrowth of microscopic organisms that clindamycin does not affect.	Patient supervision and care.

Risk	What is Known	Preventability
Inflammation of the colon (Pseudomembranous colitis)	Pseudomembranous colitis is characterized by diarrhea, abdominal pain, and fever and can occur with mostly all antibiotics. Complications from this disorder can be life-threatening. It is caused by an overgrowth of microscopic organisms that clindamycin does not affect. This condition usually occurs when antibiotics are taken by mouth or by injection, although there is the potential for it to occur with vaginal administration.	Patient supervision and care.

Important Potential Risks

Risk	What is Known
Breakdown of latex condoms or latex diaphragms if used with ovules (Weakening of latex condoms and diaphragms)	The fat covering of the ovule may weaken condoms or diaphragms that are made of latex. Thus, there is the potential for an unplanned pregnancy or transfer of a sexually transmitted disease. Because of this, use of these contraceptives is not recommended for three days after completion of therapy with clindamycin.

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Missing Information

Risk	What is Known
Use in elderly patients over 65 years of age	The use of the ovules has not been studied in patients over 65 years of age.
Use in pregnant and breastfeeding (lactating) women	The use of the ovules has not been studied in pregnant women, but the use of the cream form of vaginal clindamycin has been studied. The cream form has not been studied in the first trimester. Therefore, the use of the clindamycin ovules, just like the cream, is only recommended in the second or third trimester. When clindamycin is administered via the ovule, it is not known whether it is excreted in human milk. However, it is excreted in human milk when the drug is taken by mouth. The decision to use the ovules while breastfeeding should be made after careful consideration of the benefits and the risks.
Use in pediatric patients under 16 years of age	The use of the ovules has not been studied in patients under 16 years of age.
Use in patients with weak immune systems (immunodeficient)	The use of the ovules has not been studied in patients with weak immune systems.
Use in patients with large bowel (colon) inflammation	The use of the ovules has not been studied in patients with inflammation of the large bowel.

6.2.5. 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 the recommendations for minimizing 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 minimization measures.

This medicine has no additional risk minimisation measures.

6.2.6. Planned Post-Authorisation Development Plan

There are no studies planned.

6.2.7. Summary of Changes to the Risk Management Plan Over Time

As this is an initial RMP for this product, there are no changes to report at this time.

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