
PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Clindamycin Villerton Invest (Clindamycin Phosphate)

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

Clindamycin Villerton Invest's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Clindamycin Villerton Invest should be used.

I. The medicine and what it is used for

Clindamycin Villerton Invest is authorised for the treatment of the following serious and severe infections caused by susceptible microorganism:

- Staphylococcal bone and joint infections such as osteomyelitis and septic arthritis
- Chronic sinusitis caused by anaerobic microorganisms
- Infections of the lower respiratory tract such as:
 - aspiration pneumonia, pulmonary abscess, necrotising pneumonia and empyema.In case of suspected polymicrobial pulmonary infections, an agent with adequate activity against Gram-negative bacteria should also be given in combination to cover possible Gram-negative bacteria.
- Intra-abdominal infections such as peritonitis and abdominal abscess where the treatment of choice is clindamycin associated with an antibiotic with good activity against aerobic Gram negative bacteria.
- Pelvic and female genital infections such as PID, endometritis, perivaginal infections, tubo-ovarian abscesses, salpingitis, pelvic cellulites when simultaneously another antibiotic with good activity against aerobic Gram-negative bacteria is administered.
- Skin and soft tissue infections.

(see SmPC for the full indication).

It contains Clindamycin Phosphate as the active substance and it is given by intravenous infusion.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Clindamycin Villerton Invest, together with measures to minimise such risks and the proposed studies for learning more about Clindamycin Villerton Invest '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.

If important information that may affect the safe use of Clindamycin Villerton Invest is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Clindamycin Villerton Invest 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 Clindamycin Villerton Invest.

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).

Summary of Safety Concerns	
<i>Important Identified Risks</i>	Clostridium difficile associated diarrhea (CDAD), antibiotic-associated colitis and pseudomembranous colitis
	Antagonism between clindamycin and erythromycin
	Increased coagulation tests (PT/INR) and/or bleeding in combination with a vitamin K antagonist
	Clindamycin has been reported to appear in human breast milk
<i>Missing Information</i>	No data are available in infants less than one month old
	Adequate and well-controlled studies have not been performed in pregnant women during the first trimester.
	There are no data about the influence of clindamycin on the fertility in humans

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 Clindamycin Villerton Invest.

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

There are no studies required for Clindamycin Villerton Invest.