

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Indication: Skin infections caused by bacteria sensitive to sodium fusidate

Sodium fusidate is active against many different types of bacteria. In the majority of cases, the bacteria do not cause disease, but damage to the skin or other injury may lead to infection. Certain groups of people (infants, persons with diabetes and persons with chronic conditions that weaken the immune system) are at greater risk of infections. If infections are left untreated they may prove to be fatal. For most patients, topical antibiotic treatment is adequate.

VI.2.2 Summary of treatment benefits

Fucidin[®] impregnated dressing is used for skin infections caused by bacteria that are vulnerable to sodium fusidate. The use of sodium fusidate in the treatment of serious bacterial (staphylococcal) infections is well established. *S. aureus* bacterium is a widespread pathogen that causes a variety of infections, from minor eye and skin infections to life-threatening infections. The efficacy of Fucidin[®] impregnated dressing has been established by a number of clinical studies, supporting the approved indications and also supporting the use in children.

VI.2.3 Unknowns relating to treatment benefits

The efficacy profile of sodium fusidate has been very well established over the past decades.

The products have been used in a broad spectrum of the population and no unknowns relating to treatment benefits have been identified for these products.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known
None have been identified	Not Applicable



Important potential risks

Risk	What is known	Preventability
Hypersensitivity reactions	The active ingredient in Fucidin® impregnated dressing is sodium fusidate. Hypersensitivity reactions may occur due to sodium fusidate or any of the excipients in the product. The symptoms can vary from mild to severe, and may include swelling of skin, mucous membranes and air ways.	All active ingredients and excipients are listed in the SmPC and Package leaflet. Use of Fucidin® impregnated dressing is contraindicated in patients allergic to sodium fusidate or any of the excipients listed in the SmPC and Package leaflet.

Missing information

Risk	What is known
None has been identified	Not Applicable

VI.2.5 Summary of additional 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.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post authorisation studies are planned.

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

No changes to the Risk Management Plan have been conducted.

