

**BEROCCA® BLACKCURRANT**  
(Vitamin B Complex + Vitamin C + Minerals)  
Finland Risk Management Plan

**Part VI – Summary of Activities in the Risk Management Plan by Product**

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**PART VI**

**Summary of Activities in the Risk Management Plan by Product**

Active substances:	Vitamin B Complex + Vitamin C + Minerals
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Medicinal products to which this RMP refers:	Berocca® Blackcurrant
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Name of Marketing Authorisation Holder or Applicant:	Bayer Oy, Turku, Suomi
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Data lock point for this module

01 SEP 2017

Version number of RMP when this module was last updated

1.0

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**VI.1. Summary of Risk Management Plan for Berocca® Blackcurrant  
(Vitamin B Complex + Vitamin C + Minerals)**

This is a summary of the risk management plan (RMP) for Berocca® Blackcurrant. None of the presented risks (all considered as *identified* risks) have been recognized as an important, having impact on the favorable risk-benefit profile of Berocca® Blackcurrant, warranting further evaluation as a part of the pharmacovigilance plan, additional risk minimization activities or specific clinical recommendation for actions in the labeling.

Considering that all active ingredients available in Berocca® Blackcurrant are essential micronutrients, and that Berocca® brand products have been marketed for decades, no gaps in knowledge which may affect its safety profile have been identified.

The Berocca® Blackcurrant Summary of product characteristics gives comprehensive information on how the product should be used.

**VI.2. The Medicine and what it is used for**

Berocca® Blackcurrant contains vitamin B Complex + vitamin C + zinc, calcium and magnesium as the active ingredients and it is taken orally in the form of film-coated tablets, effervescent tablets, or chewable tablets.

Berocca® Blackcurrant is used for treatment or supplementation of:

- Deficiency and/or increased requirement of vitamin C and B vitamins.
- Deficiency and/or increased requirement of zinc.

**VI.3. Risks Associated with the Medicine and Activities to Minimise or  
further Characterise the Risks**

None of the presented risks (all estimated as identified) have been considered as important and having impact on the favorable risk-benefit balance of Berocca® Blackcurrant, or warranting further evaluation as part of the pharmacovigilance plan or additional risk minimization measures.

The routine pharmacovigilance practices, such as:

- collection, monitoring, evaluation and expeditious reporting of individual cases
- monitoring and evaluation of signals
- preparation and submission of periodic safety reports,

as well as routine risk minimization measures (i.e effective labeling) are deemed sufficient.

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**VI.3.A. List of Important Risks and Missing Information**

Not applicable

**VI.3.B. Summary of Important Risks**

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**Summary of safety concerns**

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Important identified risks	None
Important potential risks	None
Missing information	None

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**VI.3.C. Post-authorisation Development Plan**

No safety and/or efficacy post authorization studies are planned for Berocca® Blackcurrant.