



Product concept: **rhodiola rosea**

Added energy coming from nature at the push of a button

Extract FB300A from the genuine Rhodiola Rosea coming from controlled, integrated cultivation

by Finzelberg



Rhodiola Rosea – categorisation and effects

Rhodiola Rosea is referred to as what is known as an 'adaptogen'. This term subsumes plants and their preparations that help the organism better adjust to challenging situations in life. The monograph by the Committee on Herbal Products (HMPC) of the European Medicines Agency (EMA) published in 2012 also

officially categorizes Rhodiola Rosea as an adaptogen. Rhodiola Rosea extracts in compliance with the description given in the monograph thus provide the active ingredient for traditional herbal medicinal products 'for relief of the symptoms of loss of strength and weakness'.

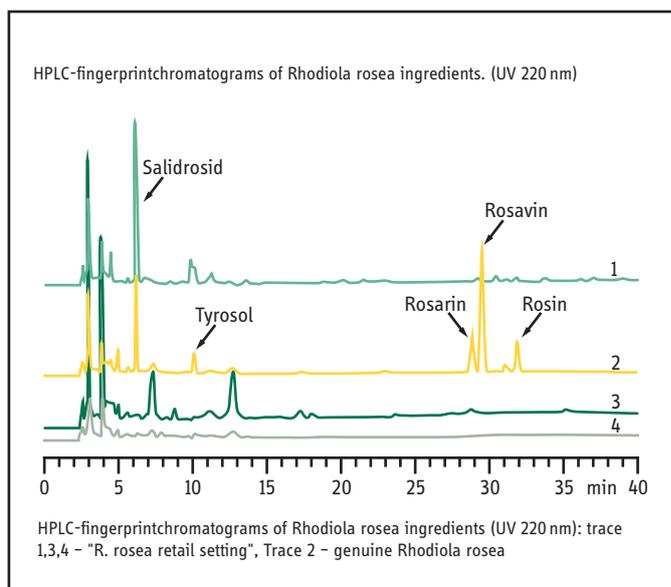
Our obligation to controlled, integrated cultivation

In nature, Rhodiola Rosea grows in the Alpine regions of Central and Eastern Europe. To harvest rootstock in sufficient size and with the typical spectrum of ingredients requires that the plants be annuals. Because Rhodiola Rosea has been on the list of rare plants since 1980, future demand for the genuine Rhodiola Rosea drug can no longer be met through collection of wild specimens alone. Individual countries have already enacted prohibitions on exports of the plant. To protect the natural resources of the

Rhodiola Rosea, cultivation of the plant is an absolute obligation for the Martin Bauer Group. This is why, since the early 1990s, the company has consistently invested in the controlled, integrated cultivation of plants of the species Rhodiola Rosea L. In 2008, the Martin Bauer Group managed to establish a large-scale cultivation operation for Rhodiola Rosea in Europe. The difficult step toward cultivation of Rhodiola Rosea L. was thus a success.

The “genuine” Rhodiola

In retail settings, one often finds mixtures of various Rhodiola species under the title “Rhodiola Rosea”. Through controlled, integrated cultivation, the Martin Bauer Group can guarantee the medicinal identity and purity of the Rhodiola species, as specified in the HMPC monograph. Hence, the active ingredient **FBA300A** meets the relevant requirements and can be used as a traditional herbal medicinal product for relief of the symptoms of loss of strength and weakness.



Benefits of FB300A Rhodiola Rosea extract:

- ▶ Careful use of natural resources
- ▶ Guarantee of identity of raw materials and extract quality
- ▶ Safe procurement of raw materials independent of cultivation regions and market trends
- ▶ Extract production in accordance with GMP
- ▶ Price stability and independence from market demand
- ▶ Everything from a single source, from the drug to the extract



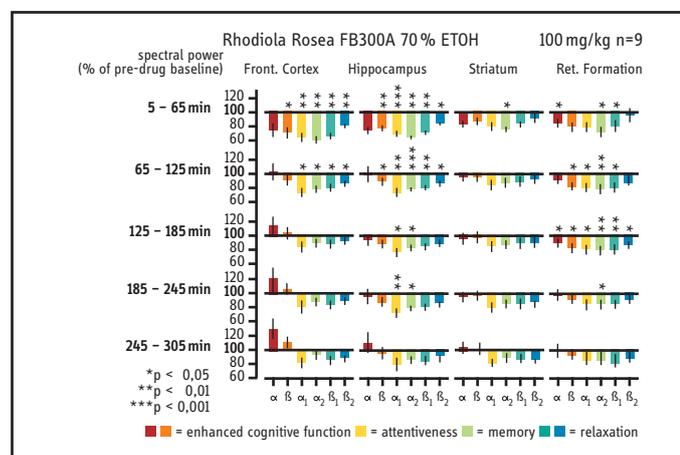
Fast onset of action– study findings

Observational study on cyclists

Among well-trained bicyclists (n=24), in a placebo-controlled study, an acute dose of 200 mg of Finzelberg Rhodiola Rosea extract led after one hour to a significant delay in exhaustion.¹ The acute performance enhancement was confirmed in another study (n=18) involving an ergometer for a dosage of 3 mg of extract per kg: lower heart rate during stress phases; longer riding performance.²

Animal study

In an animal study with rats (n=9), the effect of FB300A on the central nervous system was recorded through recordings of brain waves. The orientation of the amplitudes suggests a calming effect and enhanced performance at the same time.³



rhodiola rosea product concept phytopharmaceutical solution

- ▶ Plant material from controlled, integrated cultivation by the Martin Bauer Group
- ▶ Cultivation of **FB300A** extract from genuine Rhodiola Rosea (DEV:1.5–5:1; EtOH:70%(V/V))
- ▶ Film tablet (200 mg native extract)
- ▶ Registration dossier in CTD format

▶ Indication statement: “Traditional remedy for relief of the symptoms of loss of strength and weakness”

Daily dosage: 144 – 400 mg of native extract

Ready for takeoff

rhodiola rosea

phytopharmaceutical solutions

rhodiola rosea as a prepared product solution combines the genuine Rhodiola Rosea L. drug with extract **FB300A** for the final, modern film tablet. The documentation package in CTD format is available as a significant source of added value. This provides the documentary basis for registration and comfortable market access (Directive 2004/24/EC) in Europe. Market access beyond Europe is possible as well, thanks to our expertise with respect to **rhodiola rosea**.

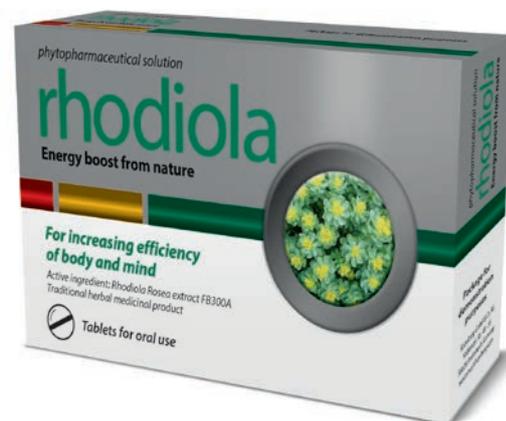
rhodiola rosea

phytonutraceutical solution

Taking national regulations into account, this option can be implemented in various countries. We support our partners through reference to the **rhodiola rosea** (THMP) concept and furnish the necessary data.

Product positioning

- ▶ **FB300A extract** as active ingredient (API) in traditional herbal medicinal products or in comparable product categories outside of Europe
- ▶ **rhodiola rosea** for the target group of 45+
- ▶ **rhodiola rosea** (THMP) as a source of added energy and as a quick source of energy
- ▶ **rhodiola rosea** to enhance physical & mental performance



Sources:

1. De Bock, K. et al., Acute Rhodiola rosea intake can improve endurance exercise performance. Intern. Journal of Sport Nutrition & Exercise Metabolism 2004, 14,298–307
2. Noreen, E.E. et al.: The Effects of an Acute Dose of Rhodiola Rosea on Endurance Exercise Performance. J Strength Cond Res. 2013, 27:839–47
3. Dimpfel, W.: Pharmacological classification of herbal extracts by means of comparison to spectral EEG signatures induced by synthetic drugs in the freely moving rat. Journal of Ethnopharmacology 2013, 149: 583–589



rhodiola rosea – Added energy from nature at the push of a button – feeling up to life’s challenges.

The product selection:

- ▶ **FB300A** – Rhodiola extract from the genuine **Rhodiola Rosea L.** coming from controlled, integrated cultivation
- ▶ **rhodiola rosea phytopharmaceutical solution** – FB300A extract pursuant in compliance with the THMP monograph plus registration dossier
- ▶ **rhodiola rosea phytonutraceutical solution** – FB300A extract as an ingredient for nutritional food

The marketing concept:

- ▶ **rhodiola rosea** – product advertisements available
- ▶ **rhodiola rosea** – package design available
- ▶ **rhodiola rosea** – video clip available

phytopharmaceutical solutions

Active phytopharmaceutical ingredients paired with regulatory support

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