



Finzelberg product concept

damiana

Natural libido

Extract FB320 Damiana

+ dossier for a unique herbal medicinal product



Our drive

Feelings of sexual well-being are a balance of physical, emotional and sociological factors. Sexual well-being involves retaining and maintaining one's own sexual health and that of one's partner. In 2006, Durex conducted a global sex study with 26,000 subjects from 26 countries. This survey found that just 38 % of respondents have sex as often as they would like to; 37 % of respondents would like to be less stressed and exhausted, and 29 % of respondents would like to have more drive. Many men (15 %) and women (30 - 60 %) suffer from a lack of sexual drive, and the causes are

diverse. Unfortunately, many sufferers are unable to speak about the taboo topic of loss of sexual drive, so we must assume that the actual number of sufferers is greater than reported.

Our drive to develop a natural aphrodisiac to counteract ebbing sexual desire was to find a holistic solution to benefit sufferers. We strive to provide a remedy that is gentle and safe.

Their opportunity

To date, there is no recognized synthetic or herbal remedy for people affected by a loss of sexual drive. Products on the market address men with the indication of "erectile dysfunction." In recent years, the market has boomed for active ingredients requiring a prescription, such as Sildenafil, Tadalafil and Vardenafil. These potency aids, however, neglect the target group most

affected: women. For the **damiana** product concept, then, there is a great opportunity to close this existing market gap with a traditional phytopharmaceutical. The product concept to be implemented as a herbal medicinal product meets the requirements of a unique phytopharmaceutical medicinal product as an aphrodisiac in the market.

Tradition, reinvigorated

Damiana occurs in nature in the form of a yellow-flowered shrub. Only the leaves are used for medicinal purposes. They contain essential oils, saps, tannins, flavonoids and hydroquinone glycosides. **Damiana** was added as a leaf-based remedy, as a tonic and aphrodisiac, in the American and Mexican medical manuals in 1874. The damiana extract FB320 forms a complex herbal multi-component system and it is the complete extract FB320 which represents the active ingredient (API) in damiana. To successfully implement the **damiana** product concept, we make use of the option of registering it as a traditional herbal medicinal product.

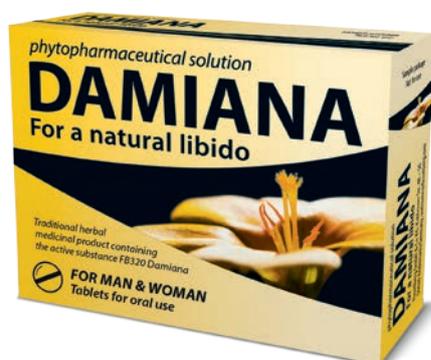
Experts at the nature network® have successfully drawn up a conclusive traditional documentation pursuant to Directives 2001/83/EC and 2004/24/EC and in compliance with Article 16c and §39b of the German Drug Act (AMG). An important step had thus been taken towards registration as a phytopharmaceutical. With this unique documentation and the resulting opportunity to apply the indication statement "traditionally used as an aphrodisiac for ebbing sexual drive," it was possible to achieve a unique selling point for the **damiana** product solution early on.



damiana product concept – ready to go

phytopharmaceutical solution

The extract FB320 was developed based on the bibliographic data; it is produced in strict application of GMP guidelines. The concept also entails the provision of a modern galenic form of application as film tablet. Special analytical testing methods were developed and validated for the extract FB320 as well as for the film tablet. Stability studies based on the guidelines prove good shelf life for the extract FB320 and for the film tablets as well. Storage instructions are not required. The dossier is available to our customers effective immediately. Our business partners can profit from the unique **damiana** product concept. Our partners thus have available to them a registration-capable documentation for market access in accordance with Directive 2004/24/EC. With our expertise for the complete, pharmaceutically oriented product concept, market access for **damiana** can be sought beyond Europe as well.



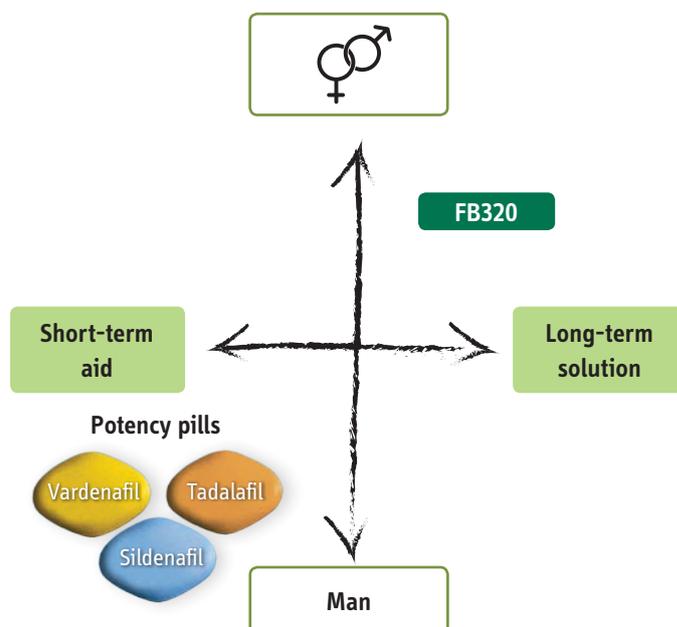
Strong positioning with unique selling points

damiana is the first product concept by Finzelberg which aims to provide an aphrodisiac in the category of traditional herbal medicinal product. In keeping with a tradition dating back more than 30 years in its application, when taken regularly, **damiana** enhances sexual drive and sexual energy. This is how **damiana** naturally contributes to the quality of life of both man and woman alike.

- ▶ **damiana** for the target group of men and women
- ▶ **damiana** as a gentle product solution, a phytopharmaceutical solution

Product concept: supportive modules on offer

- ▶ FB320 Extr. Damianae e fol. spir. sicc. (THMP)
- ▶ Film tablet (225 mg native extract)
- ▶ Individual FB testing methods for extract and film tablet
- ▶ Electronic dossier, optionally as eCTD, NeeS or in form of NeeS-capable pdf files
- ▶ Optional provision of the 3.2.S modul
- ▶ Herbal medicinal product as aphrodisiac with the possible indication statement: “traditionally used as an aphrodisiac in cases of ebbing sexual drive”





damiana – Reach out to one another with newfound desire.

The product selection:

- ▶ **FB320** - Extr. Damianae fol. spir. sicc. (THMP)
- ▶ **damiana phytopharmaceutical solution:** FB320 Damiana Extract THMP plus dossier

The marketing concept:

- ▶ **damiana** – communication concept available
- ▶ **damiana** – packaging box design available
- ▶ **damiana** – video clip available

phytopharmaceutical solutions

Active phytopharmaceutical ingredients paired with regulatory support

Finzelberg GmbH & Co. KG
Koblenzer Straße 48-56
56626 Andernach
Germany
Tel.: +49 2632 924-00
Fax: +49 2632 924-040
welcome@finzelberg.com
www.martin-bauer-group.com

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