



plantagra® – a new purified Damiana leaf
extract as a modern aphrodisiac

Erectile dysfunction

Erectile Dysfunction (ED) can mean the inability to achieve an erection, an inconsistent ability to do so, or the ability to achieve only brief erections. In our modern world erectile dysfunction is becoming a major problem. According to the National Ambulatory Medical Care Survey (NAMCS), approximately 22 out of every 1000 men in the United States sought medical attention for ED in 1999.

Lifestyle, stress and many other external influences have increased the number of patients significantly. The underlying risk factors associated with ED are common to cardiovascular disease, hypertonia and diabetes. ED incidence and severity rise with increasing age. This underlines the significance as a major health problem which strongly impacts on the quality of life of those affected, especially of older men. If ED is an ongoing problem it may cause relationship problems or affect self-confidence.

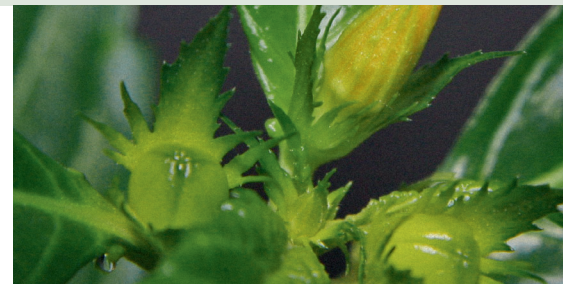
plantagra® – from tradition to modern aphrodisiac

Since ancient mankind men have tried to strengthen their sexual performance with many different herbs. One of the oldest documented remedies has been the leaves from *Turnera diffusa* var. *aphrodisiaca* (Damiana), a shrub native to Mexico, Central America and the Caribbean.

Damiana leaves have been used as an aphrodisiac, as “love potion” and to boost sexual potency by the native peoples of Mexico, including the Mayan Indians. It has been used by both males and females for sexual stimulation, to increase energy, and to treat asthma, depression, impotence and menstrual problems. Though

these indications seem to have no connection, however, the link becomes obvious when understanding imbalance of the contraction mechanisms versus relaxation of the vessels of the smooth musculature.

Throughout history different preparations and formulations have substantiated the reputation of Damiana as a valuable remedy. In the Western world Damiana preparations have been well established in different pharmacopeias (BPC, USP, HAB). The most cited indication is aphrodisiac in traditional forms or tea and fluids as well as tablets. However, proven scientific confirmation doesn't exist yet.





plantagra® – pharmacological properties

The combination of the treasury of traditionally known herbs with modern selective tools leads to a guided product development with validated manufacturing procedures. By applying different bio-assays in in-vitro-models, researchers from Finzelberg in cooperation with the Vitaplant® lab were able to identify a possible mode of action for Damiana. The inhibition of the enzyme Phosphodiesterase V (PDE-5) confirmed the same effect principle for Damiana extracts as for Sildenafil-Citrate (Viagra®).

PDE-5 inhibitors are generally not considered as aphrodisiacs because they do not have any direct effect on the libido. However, increased ability to attain an erection may be interpreted as increased sexual arousal by users of these drugs. An aphrodisiac is a substance that increases sexual desire. One link between PDE-5 inhibitors and aphrodisiacs might be Damiana.

Using PDE-5, Finzelberg was then able to further optimize its Damiana formulation, which resulted in the Damiana special extract FB9389. The IC50 value was determined with 5 µg/mL.

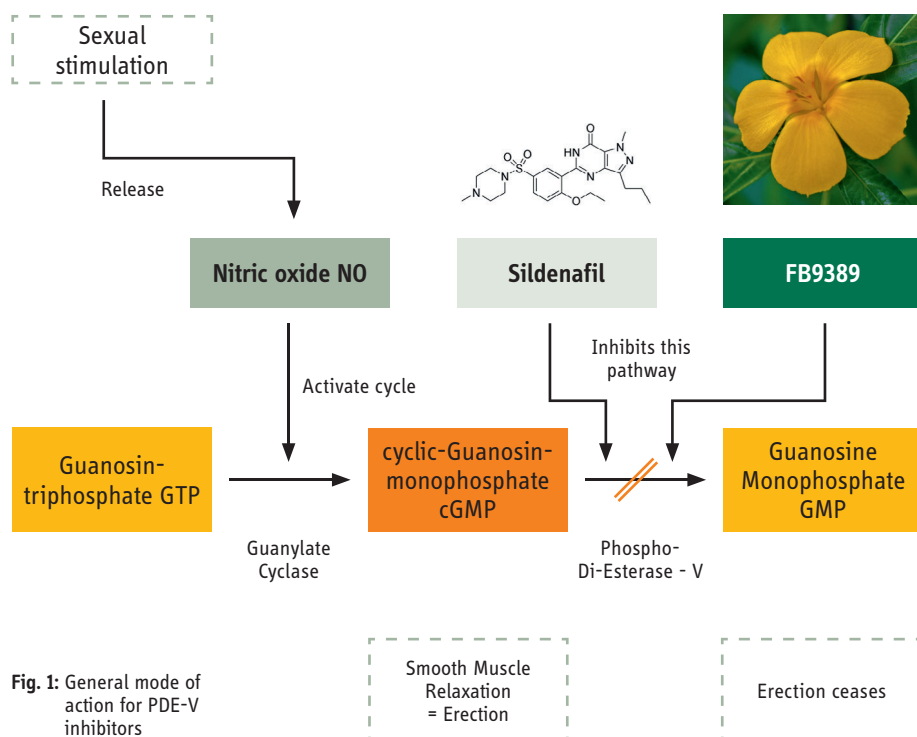


Fig. 1: General mode of action for PDE-V inhibitors



plantagra[®] – human data

In a clinical study the efficacy and safety of the Finzelberg special extract FB9389 in male subjects were tested. The study objective was to investigate whether FB9389 in 300 mg capsules is effective when given orally twice per day to male patients with mild to mild-moderate erectile dysfunction (International Index of Erectile Dysfunction, IIEF-5, score 12-21) over a period of 8 weeks.

It was concluded that the erectile functions of 66 patients were satisfactorily improved after 8 weeks' treatment with the investigated supplements using IIEF-5 questionnaires as the primary parameter (score + 4.7%), as well as using SF9 secondary questionnaires which reflect lifestyle/sexual behavior of the patients as the secondary parameter (+23%). Significant improvements were already evident after 4 weeks using the study products.

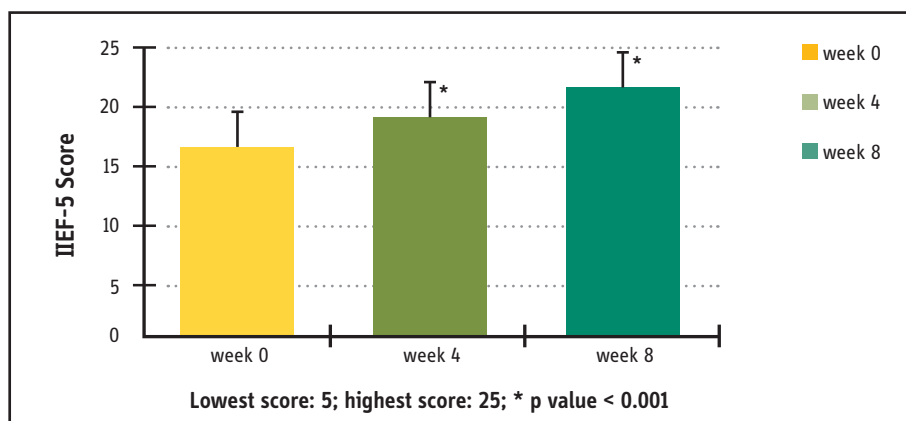


Fig. 3: Human clinical trial - changes of IIEF-5 score as primary parameter (n=66)

plantagra[®] – the marketing opportunities:

- ▶ 100 % natural remedy
- ▶ Clinically proven
- ▶ Safe, no side-effects (excellent benefit – risk ratio for a PDE-5 inhibitor)
- ▶ Traditional aphrodisiac
- ▶ Patented special extract (Finzelberg patent application WO2008071684)
- ▶ Registered trademark
- ▶ Single treatment as well as suitable in combinations
- ▶ Netto costs per day approx. 0,1 €



plantagra® – the main characteristics:

Trade name	plantagra®
Botanical part used	Turnera diffusa leaf (Damiana)
Extraction solvent	Ethanol-Water
Active markers	Acacetin
Characters	Green powder
Microbiological examination	Complies with Ph.Eur. or food requirements
Preferred galenic use	Tablets, capsules
Recommended daily dosage	200 – 600 mg per day
Safety	No toxic or gentoxic potential, safe in long term use in humans (8 weeks)

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