

5-Day Pain Away

(Tradenames: Aflapin; Apresflex; 5-LOXIN Advanced)

What is it?

- **Aflapin®** is a novel synergistic composition (Indian Patent Application No. 2229/CHE/2008) consisting of the following:
 - ***Boswellia serrata* extract selectively enriched with AKBA** (3-O-Acetyl-11-keto- β -boswellic acid)
 - Process of selectively enriching AKBA is patent protected (Indian patent #205269)
 - AKBA comprises at least 20% of Aflapin®
 - ***Boswellia serrata* non-volatile oil** (PCT/IN2009/000505)
- AKBA from Aflapin® was shown to be significantly more bioavailable than from 5-LOXIN®.

What does it do?

- Just 100 mg of Aflapin® daily (50 mg bid) for 90 days to osteoarthritic individuals in double-blind, placebo-controlled (DBPC) randomized clinical was shown to:¹
 - **Reduce pain significantly:**
 - At 7 days,
 - **13% reduction in pain** [according to Visual Analog Scale (VAS); vs no change w/P and 7% w/5-Loxin®]
 - **12% reduction in pain** (according to WOMAC pain; vs no change w/P and 9% w/5-Loxin®)
 - At 90 days,
 - **47% reduction in pain** (according VAS; vs 32% w/5-Loxin®)
 - **62% reduction in pain** (according to WOMAC pain; vs 30% w/5-Loxin®)
 - **Reduce stiffness** (according to WOMAC stiffness scores);
 - **12% at 7 days** (vs no change w/P and 30% w/5-Loxin®)
 - **60% at 90 days** (vs 42% w/5-Loxin®)
 - **Improve physical functions:**
 - At 7 days,
 - **9% improvement** (according to Lequesne's Algofunctional Index (LFI); vs no change w/P or 5-Loxin®)
 - **10% improvement** (according to WOMAC functional ability scores; vs no change w/P and 8% w/5-Loxin®)
 - At 90 days,
 - **36% improvement** (according to LFI)
 - **49% improvement** (according to WOMAC functional ability scores)
 - **Additional comments**
 - All changes described above were statistically significant ($p < 0.05$ or better)
 - Aflapin® exerted better therapeutic efficacy over 5-Loxin at 100 mg per day.
 - Unpublished data has shown that Aflapin® reduced joint pain significantly within just 5 days.

How does it work?

- **Inhibits TNF- α induced MMP-3 secretion in chondrocytes**
 - MMP-3 (matrix metalloprotease-3) is increased in osteoarthritis and is associated with the degeneration of cartilage as they are involved specifically in the degradation of cartilage.
 - *In vitro*, Aflapin® was 41% more active than 5-Loxin® at inhibiting MMP-3 secretion.
- **Inhibits TNF- α induced expression of ICAM-1 in endothelial cells**
 - ICAM-1 (intracellular adhesion molecule-1) is involved in the inflammatory process.
 - *In vitro*, Aflapin® was more active than 5-Loxin® at inhibiting ICAM-1 secretion.

How to use:

- Take 50 mg (one capsule) twice daily.

Marketing Data:

- Arthritis affects over 50 million people in the US.²
- It is estimated that 80% of the population will have radiographic evidence of OA by age 65 years, although only 60% of those will be symptomatic.³
- Osteoarthritis (OA) is the most common form of arthritis, as well as being the most common form of morbidity (disability) facing Americans adults today and has been for the past 15 years.⁴
- Medical expenditures (direct costs) for arthritis and other rheumatic conditions in 2003 were \$81 billion, up from \$51 billion in 1997.⁵

References:

¹ Sengupta K, Krishnaraju AV, Vishal AA, Mishra A, Trimurtulu G, Sarma KVS, Raychaudhuri SK, Raychaudhuri SP. *Comparative Efficacy and Tolerability of 5-Loxin® and Aflapin® Against Osteoarthritis of the Knee: A Double Blind, Randomized, Placebo Controlled Clinical Study.* **Int J Med Sci** 2010;7:366-77.

² **MMWR** 2010;59(39):1261-1265. [Data Source: 2007–2009 NHIS]

³ Green GA. *Understanding NSAIDs: from aspirin to COX-2.* **Clin Cornerstone.** 2001;3:50–60.

⁴ **MMWR** 2009;58(16):421-426. [Data Source: 2005 Survey of Income and Program Participation (SIPP)]

⁵ **MMWR** 2007;56(01):4-7. [Data Source: 2003 Medical Expenditure Panel Survey]

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