



## Voltaren® Arthritis Pain (diclofenac) – New over-the-counter approval

- On February 14, 2020, the [FDA announced](#) the approval of over-the-counter (OTC) use of [GlaxoSmithKline's Voltaren Arthritis Pain \(diclofenac\)](#) 1% topical gel for the temporary relief of arthritis pain only in the following areas: hand, wrist, elbow (upper body areas) and foot, ankle, knee (lower body areas).
  - Voltaren Arthritis Pain should not be used for strains, sprains, bruises or sports injuries. This product has not been shown to work for these types of injuries.
  - Previously, Voltaren Arthritis Pain was available [generically](#) and under the brand name [Voltaren 1%](#) as prescription for the relief of the pain of osteoarthritis (OA) of joints amenable to topical treatment, such as the knees and those of the hands.
- OA is the most common type of arthritis and increases with age. Arthritis is the swelling and tenderness of one or more joints. OA affects millions of people in the U.S., and can generally be self-diagnosed.
- Diclofenac is a nonsteroidal anti-inflammatory drug and works by reducing substances in the body that cause pain and inflammation.
- Support for OTC approval for Voltaren Arthritis Pain was based on clinical data in hand and knee OA supporting the original prescription approval.
  - The data demonstrated a consistent and appreciable onset of pain relief beginning as early as week 1 (as evidenced by appreciable improvements in pain symptoms across multiple pre-specified endpoints).
- Warnings of Voltaren Arthritis Pain include severe allergic reaction especially in people allergic to aspirin; liver damage; stomach bleeding; heart attack, heart failure and stroke; and pregnancy and breast-feeding.
- The dosage regimen of Voltaren Arthritis Pain in patients greater than 18 years of age is four times daily every day for up to 21 days.
  - For each upper body area (hand, wrist, or elbow) – squeeze out 2.25 inches (2 grams) for each dose.
  - For each lower body area (foot, ankle or knee) – squeeze out 4.5 inches (4 grams) for each dose.
  - Voltaren Arthritis Pain may take up to 7 days to work for arthritis pain; it is not for immediate relief. If no pain relief is seen in 7 days, use should be stopped.
- GlaxoSmithKline plans to launch Voltaren Arthritis Pain in the spring of 2020. Voltaren Arthritis Pain will be available in a topical 1% gel.



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