

## Triamcinolone Acetonide Extended release (TA-ER)

Peer-reviewed Publications To-date: 4/1/2021

- **A randomized, phase IIa study to assess the systemic exposure of triamcinolone acetonide following injection of extended-release triamcinolone acetonide or traditional triamcinolone acetonide into both knees of patients with bilateral knee osteoarthritis.** Kivitz A, et al. *Therapeutic Advances in Musculoskeletal Disease*. (Oct 17, 2019) Online <https://journals.sagepub.com/doi/pdf/10.1177/1759720X19881309>
- **Rescue Analgesic Medication Use by Patients Treated with Triamcinolone Acetonide Extended-Release for Knee Osteoarthritis Pain: Pooled Analysis of Three Phase 2/3 Randomized Clinical Trials.** Kivitz, A.J., Conaghan, P.G., Cinar, A. et al. *Pain Ther* (2019). <https://doi.org/10.1007/s40122-019-0125-1>
  - Click here to access the links on [Springer Link](#), along with the [Summary slide](#).
- **Efficacy of Triamcinolone Acetonide Extended-Release in Participants with Unilateral Knee Osteoarthritis: A Post Hoc Analysis** Langworthy MJ, Conaghan PG, Ruane JJ, et al. *Adv Ther* 2019. <https://link.springer.com/article/10.1007%2Fs12325-019-00944-3>
  - Click here to access the links on [SpringerLink](#) along with the [Summary Slide](#).
- **Safety and Efficacy of Repeat Administration of Triamcinolone Acetonide Extended-release in Osteoarthritis of the Knee: A Phase 3b, Open-label Study.** Spitzer, A.I., Richmond, J.C., Kraus, V.B. et al. *Rheumatol Ther* (2019). <https://doi.org/10.1007/s40744-019-0140-z>
- **Physical and Chemical Compatibility of Extended-Release Triamcinolone Acetonide (TA-ER) with Common Local Anesthetics.** Jackson, J.D., Cotton, L., Turkington, M. et al. *Adv Ther* (2019). <https://doi.org/10.1007/s12325-019-0878-2>
- **Triamcinolone acetonide extended-release in patients with osteoarthritis and type 2 diabetes: a randomized, phase 2 study.** Russell SJ, et al. Sept 6 2018 online. *Rheumatology*. <https://doi.org/10.1093/rheumatology/key265>  
<https://academic.oup.com/rheumatology/advance-article/doi/10.1093/rheumatology/key265/5091589?guestAccessKey=670fbf26-3d83-4595-a361-fcfa3d3c9193>

- **Effects of a Single Intra-Articular Injection of a Microsphere of Triamcinolone Acetonide on Knee Osteoarthritis Pain: A Double-Blinded, Randomized, Placebo-Controlled, Multinational Study.** Conaghan PG, Hunter DJ, Cohen SB, Kraus VB, Berenbaum F, Lieberman JR, Jones DG, Spitzer AI, Jevsevar DS, Katz NP, Burgess DJ, Lufkin J, Johnson JR, Bodick N; FX006-2014-008 Participating Investigators. *J Bone Joint Surg Am.* 2018 Apr 18;100(8):666-677. doi: 10.2106/JBJS.17.00154.  
<https://pubmed.ncbi.nlm.nih.gov/29664853/>
- **Local Effects Following Single and Repeat Intra-Articular Injections of Triamcinolone Acetonide Extended-Release: Results From Three Nonclinical Toxicity Studies in Dogs.** Bodick N, Williamson T, Strand V, Senter B, Kelley S, Boyce R, Lightfoot-Dunn R. *Rheumatol Ther.* 2018 Sep 10. doi: 10.1007/s40744-018-0125-3.  
<https://pubmed.ncbi.nlm.nih.gov/30203389/>
- **Brief Report: A Phase IIb Trial of a Novel Extended-Release Microsphere Formulation of Triamcinolone Acetonide for Intraarticular Injection in Knee Osteoarthritis.** Conaghan PG, Cohen SB, Berenbaum F, Lufkin J, Johnson JR, Bodick N. *Arthritis Rheumatol.* 2018 Feb;70(2):204-211. doi: 10.1002/art.40364. Epub 2017 Dec 20.  
<https://pubmed.ncbi.nlm.nih.gov/29088579/>
- **Synovial and Systemic Pharmacokinetics (PK) of Triamcinolone Acetonide (TA) Following Intra-articular (IA) Injection of an Extended-release Microsphere-based Formulation (FX006) or Standard Crystalline Suspension in Patients With Knee Osteoarthritis (OA).** Kraus VB, Conaghan PG, Aazami HA, Mehra P, Kivitz AJ, Lufkin J, Hauben J, Johnson JR, Bodick N. *Osteoarthritis Cartilage.* 2018 Jan;26(1):34-42. doi: 10.1016/j.joca.2017.10.003. Epub 2017 Oct 9.  
<https://pubmed.ncbi.nlm.nih.gov/29024802/>
- **An Intra-articular Extended-release Formulation of Triamcinolone Acetonide Prolongs and Amplifies Analgesic Effect in Patients With Osteoarthritis of the Knee: A Randomized Clinical Trial.** Bodick N, Lufkin J, Willwerth C, Kumar A, Bolognese J, Schoonmaker C, Ballal R, Hunter D, Clayman M. *J Bone Joint Surg Am.* 2015 Jun 3;97(11):877-88. doi: 10.2106/JBJS.N.00918.  
<https://pubmed.ncbi.nlm.nih.gov/26041848/>
- **Sustained Efficacy of a Single Intra-articular Dose of FX006 in a Rat Model of Repeated Localized Knee Arthritis.** Kumar A, Bendele AM, Blanks RC, Bodick N. *Osteoarthritis Cartilage.* 2015 Jan;23(1):151-60. doi: 10.1016/j.joca.2014.09.019. Epub 2014 Sep 26.  
<https://pubmed.ncbi.nlm.nih.gov/25266960/>

## Indication and Select Important Safety Information

**Indication:** ZILRETTA is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee.

**Limitation of Use:** The efficacy and safety of repeat administration of ZILRETTA have not been demonstrated.

**Contraindication:** ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids or any components of the product.

### Warnings and Precautions:

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- **Serious Neurologic Adverse Reactions with Epidural and Intrathecal Administration:** Serious neurologic events have been reported following epidural or intrathecal corticosteroid administration. Corticosteroids are not approved for this use.
- **Hypersensitivity reactions:** Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care if an anaphylactic reaction occurs.
- **Joint infection and damage:** A marked increase in joint pain, joint swelling, restricted motion, fever and malaise may suggest septic arthritis. If this occurs, conduct appropriate evaluation and if confirmed, institute appropriate antimicrobial treatment.
- Other warnings and precautions for ZILRETTA and corticosteroids as a class include, **alterations in endocrine function, cardiovascular and renal effects, increased intraocular pressure, GI perforation, alterations in bone density and behavior and mood disturbances.**

**Adverse Reactions:** The most commonly reported adverse reactions (incidence  $\geq 1\%$ ) in clinical studies included sinusitis, cough, and contusions.

Please see [ZILRETTALabel.com](http://ZILRETTALabel.com) for full Prescribing Information.

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