



APPROVAL ANNOUNCED FOR A NEW INTRANASAL PAIN MEDICATION SPRAY

Roxro Pharma has announced the approval by the Food and Drug Administration (FDA) of their intranasal formulation of ketorolac tromethamine. This drug will have the brand name of Sprix® Nasal Spray and will be the first ketorolac approved in an intranasal dose form for the short-term management of moderate to moderately severe pain. Ketorolac has traditionally been available by oral tablet or in IM injectable form under the brand name Toradol®.

This intranasal formulation can be used for up to five days. Ketorolac, a nonsteroidal anti-inflammatory drug (NSAID), is most often given in the hospital setting as an intramuscular (IM) injection and is approved by the FDA only for short-term treatment of moderately severe pain.



Cypress Care offers another point of view:

"As often occurs, this new drug will likely be prescribed by physicians treating Cypress Care's workers' compensation claimants. Although approved for only a 5-day treatment regimen, this drug will likely be prescribed more liberally," said Chip Robison, Pharm.D., director of clinical services at Cypress Care. "There is proven merit with ketorolac for addressing this type of pain. However, if Sprix® proves true to form with most pain medications, we will likely see over-zealous prescribing by a significant numbers of physicians. And due to its FDA approval for 5 to 10-day use, the Official Disability Guidelines (ODG) doctors and pharmacists have elected not to place ketorolac/Toradol® on the ODG workers' compensation formulary."

An exciting message from the early clinical trials of Sprix® is that the use of this nasal spray formulation was shown to reduce concomitant morphine use by 26% to 36% over 48 hours. Unfortunately, there is mixed acceptance with the use of ketorolac, due to its being a non-steroidal anti-inflammatory drug like ibuprofen, naproxen, aspirin, and others.

Ketorolac can cause the following:

- Peptic ulcers
- Gastrointestinal (GI) bleeding
- Perforation of the stomach or intestines
- Inhibition of platelet function, which can lead to the risk of bleeding disorders
- NSAIDs may also cause an increased risk for serious cardiovascular events, myocardial infarction and stroke - the primary reasons for the 2004 market withdrawal of Vioxx and Bextra, two highly-prescribed NSAIDs very popular in the United States



Please note: To date, Sprix® has not been launched by Roxro Pharma in the United States. Pricing data is not yet available for this product.

For questions and comments, please contact your Cypress Care account manager or email marketing@cypresscare.com.

800.419.7191
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Sources:

Jeffrey, S. (2010). FDA Approves Nasal Formulation of Ketorolac for Short-Term Pain Management. Medscape Today. Retrieved June 14, 2010 from <http://www.medscape.com/viewarticle/721939>.
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