NDC 83295-5500-01 (10-Count)
(10-Day Supply)

Apply 1 patch per day for up to 12 hours at a time.
Medicated transdermal patch can be worn up to twice per day.

Active Ingredients: Diclofenac 1.25%

Inactive Ingredients: Glucosamine

Rx Xiclo™ Transdermal Patch contains NSAID Diclofenac 1.25% and Glucosamine. This combination of ingredients is recommended for the treatment of acute pain, chronic pain, musculoskeletal pain, neuropathic pain, osteoarthritis pain, postoperative pain, low back pain inflammation, and more. Rx Xiclo™ Transdermal Patch was designed and formulated using **ODG** and ACOEM **Evidence-Based Treatment Guidelines** to improve return-to-work outcomes and help patients recover from injury. The matrix-style transdermal drug delivery system provides a controlled, constant, and extended-time release dosage administration of ingredients.

Transdermal Diclofenac 1.25% (NSAID)

In addition to their high bioavailability and long duration of action, transdermal NSAIDS have several other advantages. The review tries to understand and elucidate the use of transdermal patches, here Diclofenac, as a postoperative pain management modality. Drug delivery is one of the essential aspects of drug administration where transdermal patches are to be found equally effective when compared to oral administration of drugs. Various analgesics can be administered as patches, for example, Diclofenac – *Awachat A, Shukla D, Bhola ND. Efficacy of Diclofenac Transdermal Patch in Therapeutics: A Literature Review. Cureus. 2022 Oct 18;14(10):e30411. doi: 10.7759/cureus.30411. PMID: 36407136; PMCID: PMC9669738.*

Compared to oral administration, transdermal patches offer numerous benefits. These include avoidance of first-pass metabolism, sustained and non-rapid absorption, steady plasma levels that remain for prolonged periods, lack of patient dependence on drugs, prevention of gastric distress, and flexibility of stopping delivery of medications by simply removing the patch. – *2022 Oct 18;14(10):e30411. doi: 10.7759/cureus.30411. PMID: 36407136; PMCID: PMC9669738.*

Transdermal Diclofenac 1.25% (NSAID) (cont'd)

Future developments may make it easier to administer analgesics transdermally. Due to improved delivery, this method makes it more popular and widely used. Compared with oral treatment, the transdermal route is the most successful innovative research area in the new drug delivery system. A transdermal drug delivery system (TDDS) is the most efficient, safest, and easiest way for systemic drug delivery. – *https://pmc.ncbi.nlm.nih.gov/articles/PMC9669738/*

Transdermal patches have in the recent past been developed as innovative topical delivery systems for diclofenac and other NSAIDs, offering the advantage of sustained drug delivery[8] with reduced incidence of systemic adverse effects due to lower plasma concentrations.[9,10] – *Bhaskar H, Kapoor P, Ragini. Comparison of transdermal diclofenac patch with oral diclofenac as an analgesic: A cross over efficacy trial. 2010 Jul;1(3):158-63. doi: 10.4103/0976-237X.72783. PMID: 22114407; PMCID: PMC3220102.*
Statistical analyses revealed that there was a gradual increase in pain relief scores and a gradual decrease in pain intensity scores with the use of oral diclofenac tablets as well as with the transdermal patch. However, subjects reported that they were more comfortable using the transdermal patch particularly due to the once-a-day application and lesser frequency of systemic adverse effects. Results of this study indicate that the transdermal diclofenac patch provides as potent analgesia as the oral diclofenac tablets with the added advantage of better patient compliance and may be used for routine analgesia. The transdermal diclofenac patch is a promising analgesic modality for the management of mild to moderate pain given the evidence of its established analgesic potency with a lower incidence of systemic adverse effects. Transdermal diclofenac therapy may have a role to play in post-traumatic pain, perhaps with an increased strength of the analgesic drug in the transdermal patch. – *2010 Jul;1(3):158-63. doi: 10.4103/0976-237X.72783. PMID: 22114407; PMCID: PMC3220102.*

Diclofenac 1.25% (NSAID)

Diclofenac is recommended as a first-line treatment option for musculoskeletal pain, osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. – *ODG*
Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID) that works by inhibiting COX-1 and COX-2 enzymes within tissues locally, resulting in the reduction of prostaglandin production. – *ODG*
For acute painful conditions, a systematic review of 207 studies (32,959 patients) evaluating pharmacologic and nonpharmacologic management of acute pain from non-low back musculoskeletal injuries in adults found, for pain relief at 2 hours and symptom relief, that there was high or moderate certainty of evidence that diclofenac plus another NSAID was among the most effective treatments compared with placebo and other treatments. – *ODG*

Diclofenac 1.25% (NSAID) (cont'd)

A systematic review of 32 studies of NSAIDs for acute low back pain in adults found moderate-quality evidence that NSAIDs are more effective than placebo for short-term pain reduction and high-quality evidence that NSAIDs are more effective than placebo for short-term reduction in disability. – *ODG*
For osteoarthritis, a network meta-analysis of 137 studies (33,243 participants) evaluating the effectiveness of pharmacologic interventions and comparators for symptomatic knee osteoarthritis found, at 3 months, that diclofenac was better than placebo and acetaminophen for improvement in pain, function, and stiffness. – *ODG*

For osteoarthritis, a meta-analysis of studies evaluating topical NSAIDs for chronic musculoskeletal pain in adults comparing topical diclofenac with placebo found, at 6-12 weeks, that topical diclofenac was associated with an increase in the proportion of patients reporting clinical success (defined as a reduction in pain of at least 50% or an Osteoarthritis Research Society International Index response) compared with placebo. – *ODG*
NDSAIDs are used for pain relief for rheumatoid arthritis. – *ODG*
Diclofenac sodium is a commonly prescribed NSAID, which exhibits anti-inflammatory, analgesic and anti-pyretic activity. When used by the oral route, however, only about 50% of the absorbed dose of diclofenac becomes systemically available, due to the first pass metabolism. Also, due to the high plasma concentrations attained,[4,5] oral diclofenac carries the potential for significant adverse reactions, particularly those involving the gastrointestinal tract.[6,7] – *2010 Jul;1(3):158-63. doi: 10.4103/0976-237X.72783. PMID: 22114407; PMCID: PMC3220102.*
Topical NSAIDs are meant to deliver medication locally and superficially in musculoskeletal disorders to reduce pain, swelling, improve range of motion, and return the patient to full functional capacity as early as possible. (39, 40) (Russell 91; Mason 04). "This study demonstrates an effective treatment for patients suffering from musculoskeletal injuries (sprains and tendinitis) and is significantly more effective than placebo." – *ODG*

Topical NSAIDs are selectively recommended for treatment of chronic persistent pain where target tissues are superficially located. Topical NSAIDs provide improvement in pain and function with the avoidance of gastrointestinal adverse effects of some oral NSAIDs. – *ACOEM*
Topical NSAIDs are recommended for treatment of chronic neuropathic pain. Topical NSAIDs may be the preferred initial therapy for some patients due to the low adverse effect profile in working age adults. Topical NSAIDs provide improved pain control with negligible risk of impairments, especially cognitive, which are present with many other treatment options. Topical NSAIDs are among the best medications, especially for safety sensitive workers. – *ACOEM*

Glucosamine – Inactive Ingredient

Glucosamine is a precursor for glycosaminoglycans, and glycosaminoglycans are a major component of joint cartilage. Glucosamine supplements may help to rebuild cartilage and treat the symptoms of arthritis. In vitro studies show evidence that glucosamine reduces inflammation via inhibition of interferon gamma and Nuclear factor kappa B subunit 65 (NF-κB p65), improving the symptoms of arthritis and joint pain. – *PubChem, NCBI, NLM, NIH, DrugBank*
Osteoarthritis (OA) is a progressive and degenerative joint disease marked by loss of cartilage, bone changes, and synovial membrane inflammation. Treatment with chondroprotective drugs, such as glucosamine sulfate may offer additional benefits to nonsteroidal anti-inflammatory drugs treating the painful symptoms of OA. Glucosamine is commonly used for arthritic joint pain. – *PubChem, NCBI, NLM, NIH, DrugBank*

The administration of glucosamine, in theory, provides a building block towards the synthesis of glycosaminoglycans, slowing the progression of osteoarthritis and relieving symptoms of joint pain. Studies to this date examining the efficacy of glucosamine sulfate have been inconclusive. Glycosaminoglycans contribute to joint cartilage elasticity, strength, and flexibility. A systematic review of various studies and guidelines determined that modest improvements were reported for joint pain and function in patients taking glucosamine. – *PubChem, NCBI, NLM, NIH, DrugBank*
Glucosamine and chondroitin sulfate are used to treat osteoarthritis. The multicenter, double-blind, placebo- and celecoxib-controlled Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) evaluated their efficacy and safety as a treatment for knee pain from osteoarthritis. 1583 patients with symptomatic knee osteoarthritis /were randomly assigned. Exploratory analyses suggest that the combination of glucosamine and chondroitin sulfate may be effective in the subgroup of patients with moderate-to-severe knee pain. – *Clegg DO et al; New Eng J Med 354: 795-808 (2006)* PMID:16495392

Topical application of glucosamine and chondroitin sulfate is effective in relieving the pain from osteoarthritis (OA) of the knee and improvement is evident within 4 weeks. – *J Rheumatol. 2003 Mar;30(3):523-8. Erratum in: J Rheumatol. 2003 Nov;30(11):2512. PMID: 12610812.*

Topical and oral glucosamine/chondroitin sulfate are safe and equally effective on improving knee pain, stiffness and function. Glucosamine is beneficial as a symptomatic treatment and not as a cartilage sparing drug in the treatment of OAK. – *Yousry H. Hammad, Hala R. Magid, Mona M. Sobhy (https://www.sciencedirect.com/science/article/pii/S1110116414000623)*

The excellent safety profile of glucosamine therapy should be discussed with patients, and these supplements may serve a role as an initial treatment modality for many osteoarthritis (OA) patients. – (https://www.sciencedirect.com/science/article/pii/S0749806308005896)

Glucosamine – Inactive Ingredient (cont'd)

The modification of anti-inflammatory properties of the combined use of NSAIDs and Glucosamine in topical dosage form for degenerative and inflammatory joint diseases treatment. The high antialterative, antiexudative, and moderate antiproliferative activity of the investigated combination have been proved, allowing a balanced influence on the inflammatory process and proving useful in the treatment of degenerative and inflammatory joint diseases. – Clinical Therapeutics 2016 (https://www.sciencedirect.com/science/article/pii/S0149291816305872)