



Policy Title Diclofenac potassium (Zipsor™)

Policy Number FS.CLIN.63

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This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Diclofenac potassium (Zipsor)** is indicated for the relief of mild to moderate acute pain.

The use of Diclofenac potassium (Zipsor) requires prior authorization (i.e. clinical pharmacy and/or medical director review).

Policy description **Diclofenac potassium (Zipsor)** is a nonsteroidal anti-inflammatory drug. The exact mechanism of action is not completely understood but may involve inhibition of the cyclooxygenase (COX-1 and COX-2) pathways.

Policy guideline inclusion **Diclofenac potassium (Zipsor)** is approved when **all** of the following inclusion criteria are met:

- Documentation of pain
- Documentation of the trial and failure or contraindication/intolerance to a meloxicam-containing product and one additional oral non-steroidal anti-inflammatory drug (NSAID).

Quantity limit criteria

Diclofenac potassium (Zipsor) is approved in quantities greater than 120/30 days when the following inclusion criterion is met:

- Documentation of a randomized, double-blind, active- or placebo-controlled trial demonstrating the safety and efficacy of the requested dose for the condition submitted, where the results are published in a national peer-reviewed journal.

Policy guideline exclusion **Diclofenac potassium (Zipsor)** is denied when **any** of the following exclusion criteria are present:

- No documentation of pain.
- No documentation of the trial and failure or contraindication/intolerance to a meloxicam-containing product and one additional oral non-steroidal anti-inflammatory drug (NSAID).

Quantity limit criteria

Diclofenac potassium (Zipsor) is denied for quantities greater than 120/30 days when the following exclusion criterion is present:

- No documentation of a randomized, double-blind, active- or placebo-controlled trial demonstrating the safety and efficacy of the requested dose for the condition submitted, where the results are published in a national peer-reviewed journal.

Policy List of Applicable Drugs

Brand Name	Generic Name
Zipsor	Diclofenac potassium

Dosing and administration Refer to the specific manufacturer's prescribing information for administration and dosage details, contraindications, and Black Box warnings.

Policy references Facts and Comparisons website. [Zipsor]. Available at www.factsandcomparisons.com. Accessed April 11, 2011.
Micromedex website [Zipsor]. Available at www.micromedex.com. Accessed April 11, 2011.
Zipsor [package insert]. Xanodyne pharmaceuticals. Newport, KY. 2009.
Zipsor website. Available at www.zipsor.com. Accessed April 11, 2011.

Policy link to related policies

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