

FIRST TIME GENERIC APPROVAL

Brand Name	Pennsaid
Generic Name	diclofenac sodium
Drug Manufacturer	Apotex Corp.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

May 6, 2022

LAUNCH DATE

May 9, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 207714

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Diclofenac sodium topical solution is a nonsteroidal anti-inflammatory drug indicated for the treatment of the pain of osteoarthritis of the knee(s).

MECHANISMS OF ACTION

Diclofenac has analgesic, anti-inflammatory, and antipyretic properties.

The mechanism of action of diclofenac sodium topical solution, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2).

Diclofenac is a potent inhibitor of prostaglandin synthesis *in vitro*. Diclofenac concentrations reached during therapy have produced *in vivo* effects. Prostaglandins sensitize afferent nerves and potentiate the action of bradykinin in inducing pain in animal models. Prostaglandins are mediators of inflammation. Because diclofenac is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissues.

DOSE FORM AND STRENGTH

Diclofenac sodium topical solution, USP 2% w/w.

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DOSE & ADMINISTRATION

Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.

The recommended dose is 2 pump actuations on each painful knee, 2 times a day.

- Apply diclofenac sodium topical solution, to clean, dry skin.
- Dispense 40 mg (2 pump actuations) directly onto the knee or first into the hand and then onto the knee. Spread evenly around front, back and sides of the knee.
- Wait until the area is completely dry before covering with clothing or applying sunscreen, insect repellent, cosmetics, topical medications, or other substances.
- Until the treated knee(s) is completely dry, avoid skin-to-skin contact between other people and the treated knee(s).
- Do not get diclofenac sodium topical solution in your eyes, nose, or mouth.

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