# LOFENA™
(diclofenac potassium tablets, USP)

**25 mg**

# When you need to go LOW,
# *For relief of mild to moderate pain*

- *The FDA has recommended that NSAIDs be prescribed at their lowest effective dose for the shortest duration of time.*[1]
- *Broad indication for mild to moderate pain.*
- *Small pill size.*
- *Diclofenac sodium has been prescribed for over 30 years.*[2]

## INDICATION

LOFENA is indicated for relief of signs and symptoms of osteoarthritis and rheumatoid arthritis. LOFENA is indicated:

- For treatment of primary dysmenorrhea
- For relief of mild to moderate pain
- For relief of the signs and symptoms of osteoarthritis
- For relief of the signs and symptoms of rheumatoid arthritis

## IMPORTANT SAFETY INFORMATION ABOUT LOFENA

### WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

- Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use (see **WARNINGS**).
- LOFENA is contraindicated in the setting of coronary artery bypass graft (CABG) surgery (see **CONTRAINDICATIONS, WARNINGS**).

Gastrointestinal Bleeding, Ulceration, and Perforation

- NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events (see **WARNINGS**).

Carefully consider the potential benefits and risks of **LOFENA™** (diclofenac potassium tablets, USP) and other treatment options before deciding to use **LOFENA**. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals (see **WARNINGS: Gastrointestinal Bleeding, Ulceration, and Perforation**)

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed Warning and Medication Guide, attached.**

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## INDICATIONS AND USAGE

Carefully consider the potential benefits and risks of **LOFENA**™ (diclofenac potassium tablets, USP) and other treatment options before deciding to use **LOFENA**. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals **(see WARNINGS: Gastrointestinal Bleeding, Ulceration, and Perforation).**

**LOFENA** is indicated:

- For treatment of primary dysmenorrhea
- For relief of mild to moderate pain
- For relief of the signs and symptoms of osteoarthritis
- For relief of the signs and symptoms of rheumatoid arthritis

## PRESCRIBING INFORMATION

**WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS**

**Cardiovascular Thrombotic Events**

- **Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use (see WARNINGS).**
- **LOFENA™ are contraindicated in the setting of coronary artery bypass graft (CABG) surgery (see CONTRAINDICATIONS, WARNINGS).**

**Gastrointestinal Bleeding, Ulceration, and Perforation**

- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events (see WARNINGS).**

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

**LOFENA**™ is contraindicated in the following patients:

- Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to diclofenac or any components of the drug product **(see WARNINGS: Anaphylactic Reactions, Serious Skin Reactions).**
- History of asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients **(see WARNINGS: Anaphylactic Reactions, Exacerbation of Asthma Related to Aspirin Sensitivity)**.
- In the setting of coronary artery bypass graft (CABG) surgery **(see WARNINGS: Cardiovascular Thrombotic Events)**.

### PRECAUTIONS

**General**

**LOFENA**™ (diclofenac potassium tablets, USP) cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may lead to disease exacerbation. Patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids and the patient should be observed closely for any evidence of adverse effects, including adrenal insufficiency and exacerbation of symptoms of arthritis.

The pharmacological activity of **LOFENA** in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

**Information for Patients**

Advise the patient to read the FDA-approved patient labeling (Medication Guide) that accompanies each prescription dispensed. Inform patients, families, or their caregivers of the following information before initiating therapy with **LOFENA** and periodically during the course of ongoing therapy.

**Cardiovascular Thrombotic Events**

Advise patients to be alert for the symptoms of cardiovascular thrombotic events, including chest pain, shortness of breath, weakness, or slurring of speech, and to report any of these symptoms to their healthcare provider immediately **(see WARNINGS: Cardiovascular Thrombotic Events).**

**Gastrointestinal Bleeding, Ulceration, and Perforation**

Advise patients to report symptoms of ulcerations and bleeding, including epigastric pain, dyspepsia, melena, and hematemesis to their healthcare provider. In the setting of concomitant use of low-dose aspirin for cardiac prophylaxis, inform patients of the increased risk for the signs and symptoms of GI bleeding **(see WARNINGS: Gastrointestinal Bleeding, Ulceration, and Perforation)**.

**Hepatotoxicity**

Inform patients of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, diarrhea, jaundice, right upper quadrant tenderness, and "flu-like" symptoms). If these occur, instruct patients to stop **LOFENA** and seek immediate medical therapy **(see WARNINGS: Hepatotoxicity)**.

**Heart Failure and Edema**

Advise patients to be alert for the symptoms of congestive heart failure including shortness of breath, unexplained weight gain, or edema and to contact their healthcare provider if such symptoms occur **(see WARNINGS: Heart Failure and Edema)**.

**Anaphylactic Reactions**

Inform patients of the signs of an anaphylactic reaction (e.g., difficulty breathing, swelling of the face or throat). Instruct patients to seek immediate emergency help if these occur **(see WARNINGS: Anaphylactic Reactions)**.

**Serious Skin Reactions, Including DRESS**

Advise patients to stop taking **LOFENA** immediately if they develop any type of rash or fever and to contact their healthcare provider as soon as possible **(see WARNINGS)**.

**Female Fertility**

Advise females of reproductive potential who desire pregnancy that NSAIDs, including VOLTAREN®, may be associated with a reversible delay in ovulation **(see PRECAUTIONS: Carcinogenesis, Mutagenesis, Impairment of Fertility)**.

**Fetal Toxicity**

Inform pregnant women to avoid use of **LOFENA** and other NSAIDs starting at 30 weeks gestation because of the risk of the premature closing of the fetal ductus arteriosus. If treatment with diclofenac potassium tablets is needed for a pregnant woman between about 20 to 30 weeks gestation, advise her that she may need to be monitored for oligohydramnios, if treatment continues for longer than 48 hours **(see WARNINGS: Fetal Toxicity, PRECAUTIONS: Pregnancy)**.

**Avoid Concomitant Use of NSAIDs**

Inform patients that the concomitant use of **LOFENA** with other NSAIDs or salicylates (e.g., diflunisal, salsalate) is not recommended due to the increased risk of gastrointestinal toxicity, and little or no increase in efficacy **(see WARNINGS: Gastrointestinal Bleeding, Ulceration, and Perforation and Drug Interactions)**. Alert patients that NSAIDs may be present in "over-the-counter" medications for treatment of colds, fever, or insomnia.

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed Warning and Medication Guide, attached.**

## ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Cardiovascular Thrombotic Events **(see WARNINGS)**
- GI Bleeding, Ulceration and Perforation **(see WARNINGS)**
- Hepatotoxicity **(see WARNINGS)**
- Hypertension **(see WARNINGS)**
- Heart Failure and Edema **(see WARNINGS)**
- Renal Toxicity and Hyperkalemia **(see WARNINGS)**
- Anaphylactic Reactions **(see WARNINGS)**
- Serious Skin Reactions **(see WARNINGS)**
- Hematologic Toxicity **(see WARNINGS)**

## DRUG INTERACTIONS

### Drugs That Interfere with Hemostasis

Monitor patients with concomitant use of **LOFENA** with anti-coagulants (e.g., warfarin), antiplatelet agents (e.g., aspirin), selective serotonin reuptake inhibitors (SSRIs), and serotonin norepinephrine reuptake inhibitors (SNRIs) for signs of bleeding **(see WARNINGS: Hematological Toxicity).**

### Aspirin

Concomitant use of **LOFENA** and analgesic doses of aspirin is not generally recommended because of the increased risk of bleeding **(see WARNINGS: Hematological Toxicity)**. **LOFENA** is not a substitute for low dose aspirin for cardiovascular protection.

### ACE Inhibitors, Angiotensin Receptor Blockers, and Beta-Blockers

During concomitant use of **LOFENA** and ACE-inhibitors, ARBs, or beta-blockers, monitor blood pressure to ensure that the desired blood pressure is obtained.

During concomitant use of **LOFENA** and ACE-inhibitors or ARBs in patients who are elderly, volume-depleted, or have impaired renal function, monitor for signs of worsening renal function **(see WARNINGS: Renal Toxicity and Hyperkalemia).**

When these drugs are administered concomitantly, patients should be adequately hydrated. Assess renal function at the beginning of the concomitant treatment and periodically thereafter.

### Diuretics

During concomitant use of **LOFENA** with diuretics, observe patients for signs of worsening renal function, in addition to assuring diuretic efficacy including antihypertensive effects **(see WARNINGS: Renal Toxicity and Hyperkalemia).**

### Digoxin

During concomitant use of **LOFENA** and digoxin, monitor serum digoxin levels.

### Lithium

During concomitant use of **LOFENA** and lithium, monitor patients for signs of lithium toxicity.

### Methotrexate

During concomitant use of **LOFENA** and methotrexate, monitor patients for methotrexate toxicity.

### Cyclosporine

During concomitant use of diclofenac potassium tablets and cyclosporine, monitor patients for signs of worsening renal function.

### NSAIDs and Salicylates

The concomitant use of diclofenac with other NSAIDs or salicylates is not recommended.

### Pemetrexed

During concomitant use of **LOFENA** and pemetrexed, in patients with renal impairment whose creatinine clearance ranges from 45 mL/min to 79 mL/min, monitor for myelosuppression, renal and GI toxicity.

### CYP2C9 Inhibitors or Inducers

A dosage adjustment may be warranted when diclofenac is administered with CYP2C9 inhibitors or inducers **(see CLINICAL PHARMACOLOGY: Pharmacokinetics).**

***Please see full Prescribing Information for complete information about Drug Interactions.***

## USE IN SPECIFIC POPULATIONS

### Pregnancy

Use of NSAIDs, including **LOFENA**, can cause premature closure of the fetal ductus arteriosus and fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, limit dose and duration of **LOFENA** use between about 20 and 30 weeks of gestation and avoid **LOFENA** use at about 30 weeks of gestation and later in pregnancy **(see WARNINGS: Fetal Toxicity).**

### Infertility

Based on the mechanism of action, the use of prostaglandin mediated NSAIDs, including **LOFENA**, may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women. Consider withdrawal of NSAIDs, including **LOFENA**, in women who have difficulties conceiving or who are undergoing investigation of infertility.

### Nursing Mothers

Based on available data, diclofenac may be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for **LOFENA** and any potential adverse effects on the breastfed infant from the **LOFENA** or from the underlying maternal condition.

### Pediatric Use

The safety and effectiveness of **LOFENA** in pediatric patients has not been established.

### Geriatric Use

Elderly patients, compared to younger patients, are at greater risk for NSAID-associated serious cardiovascular, gastrointestinal, and/or renal adverse reactions. If the anticipated benefit for the elderly patient outweighs these potential risks, start dosing at the low end of the dosing range, and monitor patients for adverse effects **(see WARNINGS: Cardiovascular Thrombotic Events, Gastro-intestinal Bleeding, Ulceration, and Perforation, Hepatotoxicity, Renal Toxicity and Hyperkalemia, PRECAUTIONS: Laboratory Monitoring)**.

## OVERDOSAGE

Symptoms following acute NSAID overdosages have been typically limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which have been generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression, and coma have occurred, but were rare **(see WARNINGS: Cardiovascular Thrombotic Events, Gastrointestinal Bleeding, Ulceration, and Perforation, Hypertension, Renal Toxicity and Hyperkalemia).**

**For additional information about overdosage treatment contact a poison control center (1-800-222-1222).**

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# LOFENA™
(diclofenac potassium tablets, USP)

**25 mg**

## A LOW Dose Diclofenac Potassium Tablet

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| LOFENA DOSING (see **DOSAGE and ADMINISTRATION**) | |
|---|---|
| **Indication** | **Recommended Dosage** |
| Mild/Moderate Pain | 2 tablets TID |
| Osteoarthritis | 2 tablets BID or TID |
| Rheumatoid Arthritis | 2 tablets TID or QID |
| Dysmenorrhea | 2 tablets TID |

*Switching: Different formulations of diclofenac (diclofenac sodium enteric-coated tablets; diclofenac sodium extended-release tablets; diclofenac potassium immediate-release tablets) are not necessarily bioequivalent even if the milligram strength is the same.*


## Eligible patients with commercial insurance

**To ensure eligible patients receive $0 copay*: Ask your local LOFENA representative for Carwin Cares EMR information or visit www.carwinpharma.com for additional information**

Pharmacies are suggested based on availability of product; patients may choose to have prescriptions filled through any retail pharmacy.

*Terms and conditions may apply.

**With Carwin Cares,** the cost of LOFENA is **$0 OR $20**

WITHIN THE RANGE OF THE GENERIC YOU MAY BE CURRENTLY PRESCRIBING.

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1. Food and Drug Administration. Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs). https://www.fda.gov/media/73520/download Accessed 11/05/2021. Revised May 2016
2. Drugs @ FDA: FDA Approved Drugs. New Drug Application (NDA): 019201 Voltaren, Novartis https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019201 Accessed 11/05/21



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