Voltaren® (diclofenac sodium enteric-coated tablets) is a benzene-}
propanoic acid derivative. Voltaren is available as enterico-coated tablets of 25 mg (yellow), 50 mg (light yellow), and 75 mg (light green) for oral administration. The chemical name is 2-(2-methoxy-phenyl)-2-propionic acid, 2-methyl-1[1-(2-methyl-1-oxo-2H-1-benzopyran-4-ylmethyl) phenyl]-2-phenyl-1-propanone hydrochloride.

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CLINICAL PHARMACOLOGY

Pharmacodynamics

Voltaren is a nonsteroidal anti-inflammatory drug (NSAID). In addition, Voltaren unlike many other NSAIDs, has a direct anti-inflammatory action on the synovial tissue and is effective in the treatment and relief of the signs and symptoms of osteoarthritis.

Pharmacokinetics

Voltaren is administered enterically. The tablets are designed to ensure the delay of dissolution of the active ingredient in the stomach and the subsequent release in the intestine. Diclofenac sodium is released slowly from the enteric-coated tablets, and absorption is uniform in the intestine. However, no enteric coating is present for the first 3 to 6 hours after oral administration. Voltaren is available as enterico-coated tablets of 25 mg (yellow), 50 mg (light yellow), and 75 mg (light green) for oral administration. The chemical name is 2-(2-methoxy-phenyl)-2-propionic acid, 2-methyl-1[1-(2-methyl-1-oxo-2H-1-benzopyran-4-ylmethyl) phenyl]-2-phenyl-1-propanone hydrochloride.

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When Voltaren is administered with aspirin, its protein binding may be altered. Voltaren, like other NSAIDs, is contraindicated in patients with a history of hypersensitivity reactions to aspirin-like drugs. Patients with a history of aspirin-sensitive asthma may be at increased risk of developing aspirin sensitivity and should be used with caution in patients with preexisting angioedema. Patients with asthma may have aspirin-sensitive asthma. The use of aspirin by patients with asthma may increase the risk of clinically significant respiratory reactions. Preexisting Asthma

Voltaren, like other NSAIDs, may cause serious CV side effects, including myocardial infarction, congestive heart failure, and stroke, which can be fatal. Patients who have had a previous myocardial infarction or who are at risk of developing a heart attack may be at increased risk of experiencing a serious CV event. Patients receiving high-dose aspirin therapy (160 to 325 mg/day), or other NSAIDs that inhibit COX-2, may have an increased risk of experiencing serious CV events. Pre-existing CV conditions increase this risk. Patients should be advised to discontinue Voltaren and other NSAIDs if they develop signs of CV toxicity (e.g., chest pain, shortness of breath, weakness, slurring of speech, palpitations). When aspirin is used in combination with NSAIDs, the dose and frequency should be adjusted to attain individual patient's needs. There is a risk of serious, potentially fatal, CV events with co-administration of both aspirin and NSAIDs. Use caution when combining NSAIDs with aspirin. Patients with a history of MI or angina may be at increased risk for CV events.

Drug Interactions

Aspirin: When Voltaren is administered with aspirin, its protein binding may be altered. The clinical significance of this interaction is not known, but, as with other NSAIDs, concurrent administration of aspirin and Voltaren is not recommended because of the potential of increased adverse effects. Methotrexate: NSAIDs have been reported to increase the toxicity of methotrexate. Metabolism of methotrexate may be impaired by the NSAID, and this may increase the risk of toxicity. Cyclosporine: Voltaren, like other NSAIDs, may affect renal prostaglandin production and increase the toxicity of cyclosporine through inhibition of cyclooxygenase. Cyclosporine levels may increase in patients taking cyclosporine in conjunction with Voltaren, and concurrent therapy with Voltaren may increase cyclosporine’s nephrotoxicity. Cyclosporine toxicity should be monitored in cyclosporine treated patients. ACE Inhibitors: Reports suggest that NSAID may diminish the antihypertensive effect of ACE inhibitors (angiotensin converting enzyme inhibitors). Great care should be taken in considering patients taking Voltaren concurrently with ACE inhibitors. Furosemide: Clinical studies, as well as post-marketing observations, have shown that furosemide can reduce the antihypertensive effects of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis by Voltaren. In patients taking furosemide with NSAIDs, the patient should be observed closely for signs of renal failure (e.g., azotemia, oliguria, anuria). Close monitoring is recommended. Lithium: NSAIDs have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean lithium elimination half-life increased 15% and the renal clearance was decreased by approximately 20%. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID. Thus, when NSAIDs and lithium are administered concurrently, subjects should be observed closely for signs of lithium intoxication. Other adverse reactions which occur rarely are:

OVERDOSAGE

Symptoms following acute NSAID overdoses are usually mild and may include abdominal pain, dyspepsia, constipation, diarrhea, nausea, vomiting, and epigastric pain. Serious adverse reactions in nursing infants from Voltaren, a decision should be made whether to discontinue nursing or to discontinue the drug or to alter the patient’s NSAI therapy. The importance of the drug to the mother should be considered when nursing infants are exposed. In patients taking Voltaren, the GCS and a chemistry profile (including hematocrit levels) should be checked periodically. If clinical signs and symptoms consistent with fever or renal dysfunction develop, systemic manifestations such as hypotension or edema, nausea, vomiting, or foamy urine, should be evaluated promptly. Patients should be alert for the signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indication of signs or symptoms. Electrolyte abnormalities may be caused by excessive or inadequate fluid intake, and by diuretics. Patients should be advised to increase their fluid intake and to avoid diuretics. Electrolyte abnormalities may be caused by excessive or inadequate fluid intake, and by diuretics. Patients should be advised to increase their fluid intake and to avoid diuretics.

Voltaren is available only with prescription (Rx). It is not known whether this drug is excreted in human milk. Because it is not known whether Voltaren affects milk production or if it is also excreted along with the milk, a decision should be made whether to discontinue nursing or to discontinue the drug or to alter the patient’s NSAI therapy. The importance of the drug to the mother should be considered when nursing infants are exposed. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. There are no adequate and well-controlled studies in pregnant women. 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Medication Guide
for
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)
(See the end of this Medication Guide for a list of prescription NSAID medicines.)

What is the most important information I should know about medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

NSAID medicines may increase the chance of a heart attack or stroke that can lead to death. This chance increases:
• with longer use of NSAID medicines
• in people who have heart disease

NSAID medicines should never be used right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

NSAID medicines can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Ulcers and bleeding:
• can happen without warning symptoms
• may cause death

The chance of a person getting an ulcer or bleeding increases with:
• taking medicines called “corticosteroids” and “anticoagulants”
• longer use
• smoking
• drinking alcohol
• older age
• having poor health

NSAID medicines should only be used:
• exactly as prescribed
• at the lowest dose possible for your treatment
• for the shortest time needed

What are Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?
NSAID medicines are used to treat pain and redness, swelling, and heat (inflammation) from medical conditions such as:
• different types of arthritis
• menstrual cramps and other types of short-term pain

Who should not take a Non-Steroidal Anti-Inflammatory Drug (NSAID)?
Do not take an NSAID medicine:
• if you had an asthma attack, hives, or other allergic reaction with aspirin or any other NSAID medicine
• for pain right before or after heart bypass surgery

Tell your healthcare provider:
• about all of your medical conditions.
• about all of the medicines you take. NSAIDs and some other medicines can interact with each other and cause serious side effects. Keep a list of your medicines to show to your healthcare provider and pharmacist.
• if you are pregnant. NSAID medicines should not be used by pregnant women late in their pregnancy.
• if you are breastfeeding. Talk to your doctor.
What are the possible side effects of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)?

**Serious side effects include:**

- heart attack
- stroke
- high blood pressure
- heart failure from body swelling (fluid retention)
- kidney problems including kidney failure
- bleeding and ulcers in the stomach and intestine
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- liver problems including liver failure
- asthma attacks in people who have asthma

**Other side effects include:**

- stomach pain
- constipation
- diarrhea
- gas
- heartburn
- nausea
- vomiting
- dizziness

Get emergency help right away if you have any of the following symptoms:

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body

Stop your NSAID medicine and call your healthcare provider right away if you have any of the following symptoms:

- nausea
- more tired or weaker than usual
- itching
- your skin or eyes look yellow
- stomach pain
- flu-like symptoms

These are not all the side effects with NSAID medicines. Talk to your healthcare provider or pharmacist for more information about NSAID medicines.

Other information about Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

- Aspirin is an NSAID medicine but it does not increase the chance of a heart attack. Aspirin can cause bleeding in the brain, stomach, and intestines. Aspirin can also cause ulcers in the stomach and intestines.
- Some of these NSAID medicines are sold in lower doses without a prescription (over-the-counter). Talk to your healthcare provider before using over-the-counter NSAIDs for more than 10 days.

**NSAID medicines that need a prescription**

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Tradename</th>
</tr>
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<tbody>
<tr>
<td>Celecoxib</td>
<td>Celebrex</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>Cataflam, Voltaren, Arthrotec (combined with misoprostol)</td>
</tr>
<tr>
<td>Diflunisal</td>
<td>Dolobid</td>
</tr>
<tr>
<td>Etodolac</td>
<td>Lodine, Lodine XL</td>
</tr>
<tr>
<td>Fenoprofen</td>
<td>Nalfon, Nalfon 200</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>Ansaid</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Motrin, Tab-Profen, Vicoprofen* (combined with hydrocodone), Combunox (combined with oxycodone)</td>
</tr>
<tr>
<td>Indomethacin</td>
<td>Indocin, Indocin SR, Indo-Lemmon, Indomethagan</td>
</tr>
<tr>
<td>Ketoprofen</td>
<td>Druvail</td>
</tr>
<tr>
<td>Ketorolac</td>
<td>Toradol</td>
</tr>
<tr>
<td>Mefenamic Acid</td>
<td>Ponstel</td>
</tr>
<tr>
<td>Meloxicam</td>
<td>Mobic</td>
</tr>
<tr>
<td>Nabumetone</td>
<td>Relafen</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Naprosyn, Anaprox, Anaprox DS, EC-Naprosyn, Naprelan, Naprapac (copackaged with lansoprazole)</td>
</tr>
<tr>
<td>Oxaprozin</td>
<td>Daypro</td>
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<tr>
<td>Piroxicam</td>
<td>Feldene</td>
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<tr>
<td>Sulindac</td>
<td>Clinoril</td>
</tr>
<tr>
<td>Tolmetin</td>
<td>Tolectin, Tolectin DS, Tolectin 600</td>
</tr>
</tbody>
</table>

* Vicoprofen contains the same dose of ibuprofen as over-the-counter (OTC) NSAIDs, and is usually used for less than 10 days to treat pain. The OTC label warns that long term continuous use may increase the risk of heart attack or stroke.

This Medication Guide has been approved by the U.S. Food and Drug Administration.