Diclofenac sodium enteric-coated tablets

MEDICATION GUIDE

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine talk to your doctor, pharmacist, or health care provider.

What is this medicine?
DICLOFENAC (dye KLOE fen ak) is a non-steroidal anti-inflammatory drug (NSAID). It is used to reduce swelling and to treat pain. It may be used to treat osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?
Take this medicine by mouth with food and with a full glass of water. Do not crush or chew the medicine. Follow the directions on the prescription label. Take your medicine at regular intervals. Do not take your medicine more often than directed. Long-term, continuous use may increase the risk of heart attack or stroke.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. Special care may be needed.

Elderly patients over 65 years old may have a stronger reaction and need a smaller dose.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What if I miss a dose?
If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?
They need to know if you have any of these conditions:
• Asthma, especially aspirin sensitive asthma
• Coronary artery bypass graft (CABG) surgery within the past 2 weeks
• Drink more than 3 alcohol containing drinks a day
• Heart disease or circulation problems like heart failure or leg edema (fluid retention)
• High blood pressure
• Kidney disease
• Liver disease
• Stomach bleeding or ulcers
• An unusual or allergic reaction to diclofenac, aspirin, other NSAIDs, other medicines, foods, dyes, or preservatives
• Pregnant or trying to get pregnant
• Breast-feeding

What may interact with this medicine?
Do not take this medicine with any of the following medications:
• Cidofovir
• Ketorolac
• Methotrexate

This medicine may also interact with the following medications:
• Alcohol
• Aspirin and aspirin like medicines
• Cyclosporine
• Diuretics
• Lithium
• Medicines for blood pressure
• Medicines for osteoporosis
• Medicines that affect platelets
• Medicines that treat or prevent blood clots like warfarin
• NSAIDs, medicines for pain and inflammation, like ibuprofen or naproxen
• Pemetrexed
• Steroid medicines like prednisone or cortisone
This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:

- Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
- Black or bloody stools, blood in the urine or vomit
- Blurred vision
- Chest pain
- Difficulty breathing or wheezing
- Nausea or vomiting
- Slurred speech or weakness on one side of the body
- Unexplained weight gain or swelling
- Unusually weak or tired
- Yellowing of eyes or skin

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):

- Constipation
- Diarrhea
- Dizziness
- Headache
- Heartburn

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Tell your doctor or health care professional if your pain does not get better. Talk to your doctor before taking another medicine for pain. Do not treat yourself.

This medicine does not prevent heart attack or stroke. In fact, this medicine may increase the chance of a heart attack or stroke. The chance may increase with longer use of this medicine and in people who have heart disease. If you take aspirin to prevent heart attack or stroke, talk with your doctor or health care professional.

Do not take medicines such as ibuprofen and naproxen with this medicine. Side effects such as stomach upset, nausea, or ulcers may be more likely to occur. Many medicines available without a prescription should not be taken with this medicine.

This medicine can cause ulcers and bleeding in the stomach and intestines at any time during treatment. Do not smoke cigarettes or drink alcohol. These increase irritation to your stomach and can make it more susceptible to damage from this medicine. Ulcers and bleeding can happen without warning symptoms and can cause death.

You may get drowsy or dizzy. Do not drive, use machinery, or do anything that needs mental alertness until you know how this medicine affects you. Do not stand or sit up quickly, especially if you are an older patient. This reduces the risk of dizzy or fainting spells.

This medicine can cause you to bleed more easily. Try to avoid damage to your teeth and gums when you brush or floss your teeth.

Where should I keep my medicine?

Keep out of the reach of children.

Store at room temperature below 30 degrees C (86 degrees F). Protect from moisture. Keep container tightly closed. Throw away any unused medicine after the expiration date.

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