These are not all the possible side effects of diclofenac sodium extended-release tablets. Other side effects may also occur in some patients. If any of these side effects become serious, or if any new side effects appear, tell your prescriber or call him immediately.

Diclofenac sodium extended-release tablets may cause serious skin reactions that may be fatal. These reactions are more common in people who have certain genetic traits. Do not continue diclofenac sodium extended-release if you have a skin rash, sores, fever, or joint pain along with a skin rash, sores, or fever. See "Skin Reactions" for more information.

Diclofenac sodium extended-release tablets may cause serious skin reactions. These reactions can occur at any time during treatment with diclofenac. Skin reactions that occur may be life-threatening, and may require hospitalization with replacement of blood elements or replacement of liver or kidney function.

Severe skin reactions can occur within a few weeks of starting treatment, but can occur at any time during treatment with diclofenac. You should stop taking diclofenac sodium extended-release and see your prescriber if you develop any skin rash, sores, fever, or joint pain along with a skin rash, sores, or fever. Contact your prescriber immediately if you experience any skin rash, sores, fever, or joint pain along with a skin rash, sores, or fever. If the prescriber tells you to stop taking diclofenac sodium extended-release, do not start taking any other NSAIDs or COX-2 inhibitors without first talking to your prescriber.

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Serious skin reactions that may be fatal can occur at any time during treatment with diclofenac. Skin reactions can be preceded by fever, chills, or flu-like symptoms. You should stop taking diclofenac sodium extended-release and see your prescriber if you develop any skin rash, sores, fever, or joint pain along with a skin rash, sores, or fever. Contact your prescriber immediately if you experience any skin rash, sores, fever, or joint pain along with a skin rash, sores, or fever. If the prescriber tells you to stop taking diclofenac sodium extended-release, do not start taking any other NSAIDs or COX-2 inhibitors without first talking to your prescriber.

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Respiratory System: nervousness, paresthesia, somnolence, tremors, vertigo

Body as a Whole:

Urogenital System:

Nervous System:

thrombocytopenia

Metabolic and Nutritional:

Hemic and Lymphatic System:

Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headaches, increased bleeding time, pruritus, rashes and tinnitus.

Cardiovascular System:

Dissemination Effects:

Other side effects include: 

• problems including liver failure
• asthma attacks in people who have asthma

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

• difficulty breathing 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:

• more tired or weaker than usual
• itching
• your skin or eyes look yellow
• stomach pain

Drug Interactions:

Aspirin, indomethacin, indomethacin, ibuprofen, ketoprofen, ketorolac, meclofenamate, meclofenamate, niflumic acid, naproxen, piroxicam, rifampin, rofecoxib, sulindac, tenoxicam

Serious side effects include:

• swelling of the arms and legs, hands and feet
• weakness or numbness in the legs or around the waist
• trouble seeing or changing color in your urine
• abdominal pain or tenderness
• black, tarry, or bloody stools
• unusual bleeding
• unusual bruising
• fever
• chills
• sweats

There are not all the side effects of NSAIDs. Talk to your healthcare provider or pharmacist for more information about NSAID medicines. Call your doctor's medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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 or stroke. Aspirin can cause bleeding in the brain, stomach, and intestines.
• NSAIDs 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:

Diclofenac Sodium Extended-Release Tablets, USP are available as follows:

• 50 mg—once extended-release dosage strength is the same.
• 100 mg—once extended-release dosage strength is the same.

For the relief of osteoarthritis, the recommended dosage is 100 mg q.d.

These effects are self-limiting and resolution of symptoms is common. If the symptoms persist, the dose and frequency should be adjusted to suit an individual patient's needs.

WARNINGS, Renal Effects

Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain and are rarely serious. Serious effects may occur following ingestion of more than 14 grams (2.5 times the usual adult daily dose) of ibuprofen. Anaphylactic reactions may occur but are rare. In a post-marketing study involving 1257 NSAID-exposed women who were more than 3 months from their last menses, 4.3% had positive pregnancy tests and 0.9% had adverse maternal outcomes and 0.9% had adverse fetal outcomes. Some effect on maternal or fetal outcomes are likely to occur from exposure to ibuprofen during the second and third trimesters. The risk of these effects during second and third trimester of pregnancy is unknown. In animals, ibuprofen has been shown to be embryotoxic at doses near the maternal toxic dose. Reproductive studies conducted in rats and rabbits have not demonstrated evidence of developmental abnormalities. However, human reproduction studies are not available at this time. Use of ibuprofen during pregnancy should be avoided.