

Medication Guide
Diclofenac Potassium (dye kloef' fen ak poe tas' ee um) for Oral Solution

What is the most important information I should know about diclofenac potassium for oral solution?

Diclofenac potassium for oral solution contains diclofenac (a non-steroidal anti-inflammatory drug or NSAID).

NSAIDs, including diclofenac potassium for oral solution, can cause serious side effects, including:

- **Increased risk of a heart attack or stroke that can lead to death.** This risk may happen early in treatment and may increase:
 - o with increasing doses of NSAIDs
 - o with longer use of NSAIDs

Do not take NSAIDs, including diclofenac potassium for oral solution, right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

Avoid taking NSAIDs, including diclofenac potassium for oral solution, after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- **Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:**
 - o anytime during use
 - o without warning symptoms
 - o that may cause death

The risk of getting an ulcer or bleeding increases with:

- o past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
- o taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
- o increasing doses of NSAIDs
- o older age
- o longer use of NSAIDs
- o poor health
- o smoking
- o advanced liver disease
- o drinking alcohol
- o bleeding problems

Diclofenac potassium for oral solution should only be used:

- o exactly as prescribed
- o at the lowest dose possible for your treatment
- o for the shortest time needed

What is diclofenac potassium for oral solution?

Diclofenac potassium for oral solution is a prescription medicine used to treat migraine attacks in adults. It does not prevent or lessen the number of migraines you have, and it is not for other types of headaches. Diclofenac potassium for oral solution contains diclofenac potassium (a non-steroidal anti-inflammatory drug or NSAID).

How should I take diclofenac potassium for oral solution?

Take diclofenac potassium for oral solution exactly as your healthcare provider tells you to take it.

Take 1 dose of diclofenac potassium for oral solution to treat your migraine headache:

- remove one single dose packet
- open packet only when you are ready to use it
- empty contents of packet into 1 to 2 ounces (30 to 60 mL) of water
- mix well and drink the water and powder mixture
- throw away empty packet in a safe place and out of the reach of children.
- taking diclofenac potassium for oral solution with food may cause a reduction in effectiveness compared to taking diclofenac potassium for oral solution on an empty stomach
- do not take more diclofenac potassium for oral solution than directed by your healthcare provider. In case of overdose, get medical help or contact a Poison Control Center right away

Who should not take diclofenac potassium for oral solution? Do not take diclofenac potassium for oral solution:

- if you have had an asthma attack, hives, or other allergic reaction with aspirin, diclofenac, or any other NSAIDs.
- right before or after heart bypass surgery.

Before taking diclofenac potassium for oral solution, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have a history of stomach ulcer or bleeding in your stomach or intestines
- have any allergies to any medicines
- have chest pain, shortness of breath, irregular heartbeats
- have high blood pressure
- have asthma
- are pregnant, think you might be pregnant, or are trying to become pregnant. Taking NSAIDs, including diclofenac potassium for oral solution, at about 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. **You should not take NSAIDs after about 30 weeks of pregnancy.**
- are breastfeeding or plan to breastfeed.
- have a headache that is different from your usual migraine

Tell your healthcare provider about all of the medicines you take, including prescription or over-the-counter medicines, vitamins or herbal supplements. NSAIDs, like diclofenac potassium for oral solution, and some other medicines can interact with each other and cause serious side effects. **Do not start taking any new medicine without talking to your healthcare provider first.**

Especially tell your doctor if you take:

- aspirin
- any anticoagulant medicines (warfarin, Coumadin, Jantoven)

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

What are the possible side effects of diclofenac potassium for oral solution?

Diclofenac potassium for oral solution can cause serious side effects, including:

See “What is the most important information I should know about diclofenac potassium for oral solution?”

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- 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
- asthma attacks in people who have asthma
- medication overuse headaches. Some people who use too much diclofenac potassium for oral solution may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with diclofenac potassium for oral solution.

- **Other side effects of NSAIDs include:** stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

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

- shortness of breath or trouble breathing
- chest pain
- weakness in one part or side of your body
- slurred speech
- swelling of the face or throat

Stop taking diclofenac potassium for oral solution and call your healthcare provider right away if you get any of the following symptoms

- nausea that seems out of proportion to your migraine
- sudden or severe pain in your belly
- more tired or weaker than usual
- diarrhea
- itching
- your skin or eyes look yellow
- indigestion or stomach pain
- vomit blood
- there is blood in your bowel movement or it is black and sticky like tar
- unusual weight gain
- more tired or weaker than usual
- skin rash or blisters with fever
- swelling of the arms, legs, hands and feet
- flu-like symptoms

If you take too much of your NSAID, call your healthcare provider or get medical help right away.

These are not all the possible side effects of NSAIDs. For more information, ask your healthcare provider or pharmacist about NSAIDs.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Other information about NSAIDs

- Aspirin is an NSAID 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 NSAIDs 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.

General information about the safe and effective use of NSAIDs Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NSAIDs for a condition for which it was not prescribed. Do not give NSAIDs to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information about NSAIDs, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about NSAIDs that is written for health professionals.

Manufactured by: **Umedica Laboratories Pvt. Ltd.**

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

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Additional Swatches:

 **CUTTER / DO NOT PRINT DIELINE LINES**