

Brightside Specialty Pharmacy

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Patient Education for DICLOFENAC SODIUM 1% GEL

May cause photosensitive reactions Use sunscreen Report signs of liver trouble to doctor promptly (jaundice etc) Low dose aspirin prophylaxis okay. Otherwise do not use w/ASA/NSAIDs Wash hands after applying Dispense & explain patient package insert and medication guide. Avoid contact with mucus membranes. May increase risk of heart attack, stroke or GI bleeding. Avoid use during first and third trimesters of pregnancy.

Skin may be more prone to sunburn; Use sunscreen Call MD if new abdominal pain/yellowing eyes/skin May take low dose daily aspirin if directed by MD Wash hands after applying Important to read patient package insert& med guide Avoid contact with eyes, nose, and mouth. Watch for bleeding, heart attack or stroke signs. Avoid use in 1st & 3rd trimesters of pregnancy.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

DICLOFENAC 1% - TOPICAL

(dye-KLOE-fen-ak)

COMMON BRAND NAME(S):

Voltaren

WARNING:

Nonsteroidal anti-inflammatory drugs (including

diclofenac) may rarely increase the risk for a heart attack or stroke. This effect can happen at any time while using this drug but is more likely if you use it for a long time. The risk may be greater in older adults or if you have heart disease or increased risk for heart disease (for example, due to smoking, family history of heart disease, or conditions such as high blood pressure or diabetes). Do not use this drug right before or after heart bypass surgery (CABG).

Also, this drug may rarely cause serious (rarely fatal) bleeding from the stomach or intestines. This side effect can occur without warning symptoms at any time while using diclofenac. Older adults may be at higher risk for this effect. (See also Precautions and Drug Interactions sections.)

Stop using diclofenac and get medical help right away if you notice any of the following rare but very serious side effects: stomach/abdominal pain that doesn't go away, black/bloody stools, vomit that looks like coffee grounds, chest/jaw/left arm pain, shortness of breath, unusual sweating, confusion, weakness on one side of the body, sudden vision changes, trouble speaking.

Talk with your doctor or pharmacist about the benefits and risks of using this medication.

USES:

See also Warning section.

This medication is used to relieve joint pain from arthritis.

Diclofenac belongs to a class of drugs known as nonsteroidal anti-inflammatory drugs (NSAIDs).

If you are treating a chronic condition such as arthritis, ask your doctor about non-drug treatments and/or using other medications to treat your pain.

HOW TO USE:

Read the Medication Guide and Patient Instructions

For Use provided by your pharmacist before you start using diclofenac and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

This medication is for use on the skin only. To measure the right dose, use the dosing card(s) provided with the medication. Place a dosing card on a flat surface so that you can read the print on the card. Squeeze an even line of the medication from the tube onto the dosing card, using the marks on the card to measure the prescribed dose. Gently rub the medication into the entire affected joint, usually 4 times daily or as directed by your doctor. You may use the dosing card to apply the medication. Do not apply the medication on skin that has cuts, infections, or rashes.

If the package instructions direct you to reuse the dosing card, then after each use, hold the card with your fingertips, rinse, and dry. When you are ready to discard the dosing card, fold the card in half with the medication side inside and throw away out of the reach of children and pets. Wash your hands after using the medication unless you are using it to treat the hands. Do not shower, bathe, or wash any treated areas for at least an hour after applying the medication. Wait at least 10 minutes before covering the treated area with gloves or clothing. Do not wrap, bandage, or apply heat (such as a heating pad) to the treated area.

The dosage is based on your medical condition and response to treatment. Do not apply more than 16 grams of diclofenac per day to any single joint of the lower body (such as knee, ankle, foot). Do not apply more than 8 grams of diclofenac per day to any single joint of the upper body (such as hand, wrist, elbow). No matter how many joints you are treating, do not use more than a total of 32 grams of diclofenac per day.

Discuss the risks and benefits of using this drug with your doctor or pharmacist. To reduce the risk of side effects, use this medication at the lowest effective dose for the shortest possible time. Do not increase your dose, use it more often than prescribed, or apply the medication to any area not prescribed by your doctor.

Do not get the medication in the eyes, nose, or mouth. If you do get the medication in those areas, flush with plenty of water. Contact your doctor right away if irritation lasts.

For certain conditions (such as arthritis), it may take up to 2 weeks of using this drug regularly until you get the full benefit.

If you are using this drug "as needed" (not on a regular schedule), remember that pain medications work best if they are used as the first signs of pain occur. If you wait until the pain has worsened, the medication may not work as well.

Tell your doctor if your pain lasts or gets worse.

SIDE EFFECTS:

See also Warning section.

Skin irritation/redness may occur at the application site. If this effect lasts or gets worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

Tell your doctor right away if you have any serious side effects, including: signs of kidney problems (such as change in the amount of urine), symptoms of heart failure (such as swelling ankles/feet, unusual tiredness, unusual/sudden weight gain).

This drug may rarely cause serious (possibly fatal) liver disease. Get medical help right away if you have any symptoms of liver damage, including: nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine.

A very serious allergic reaction to this drug is rare.

However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: fever, swollen lymph nodes, rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before using diclofenac, tell your doctor or pharmacist if you are allergic to it; or to aspirin or other NSAIDs (such as ibuprofen, naproxen, celecoxib); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: asthma, aspirin-sensitive asthma (a history of worsening breathing with runny/stuffy nose after taking aspirin or other NSAIDs), liver disease, stomach/intestine problems (such as bleeding, ulcers), heart disease (such as previous heart attack), high blood pressure, stroke, swelling (edema, fluid retention), blood disorders (such as anemia), bleeding/clotting problems, growths in the nose (nasal polyps).

Kidney problems can sometimes occur with the use of NSAID medications, including diclofenac. Problems are more likely to occur if you are dehydrated, have heart failure or kidney disease, are an older adult, or if you take certain medications (see also Drug Interactions section). Drink plenty of fluids as directed by your doctor to prevent dehydration and tell your doctor right away if you have a change in the amount of urine.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

This medicine may cause stomach bleeding. Daily use of alcohol and tobacco while using this medicine may increase your risk for stomach bleeding. Limit alcohol and stop smoking. Ask your doctor or pharmacist about how much alcohol you may safely drink.

This medication may make the treated area more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Wear protective clothing when outdoors. Ask your doctor whether you should use sunscreen along with this medication. Tell your doctor right away if you get sunburned or have skin blisters/redness.

Older adults may be at greater risk for stomach/intestinal bleeding, kidney problems, heart attack, and stroke while using this drug.

Before using this medication, women of childbearing age should talk with their doctor(s) about the benefits and risks. Tell your doctor if you are pregnant or if you plan to become pregnant. This medication may harm an unborn baby and cause problems with normal labor/delivery. It is not recommended for use in pregnancy from 20 weeks until delivery. If your doctor decides that you need to use this medication between 20 and 30 weeks of pregnancy, you should use the lowest effective dose for the shortest possible time. You should not use this medication after 30 weeks of pregnancy.

It is unknown if this form of diclofenac passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share

it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: aliskiren, ACE inhibitors (such as captopril, lisinopril), angiotensin II receptor blockers (such as losartan, valsartan), cidofovir, corticosteroids (such as dexamethasone, prednisone), lithium, methotrexate, other products applied to treated skin, "water pills" (diuretics such as furosemide).

This medication may increase the risk of bleeding when used with other drugs that also may cause bleeding. Examples include antiplatelet drugs such as clopidogrel, "blood thinners" such as dabigatran/enoxaparin/warfarin, erlotinib, among others.

Check all prescription and nonprescription medicine labels carefully since many medications contain pain relievers/fever reducers (aspirin, NSAIDs such as ibuprofen, naproxen, or ketorolac). These drugs are similar to diclofenac and may increase your risk of side effects if taken together. However, if your doctor has directed you to take low-dose aspirin to prevent heart attack or stroke (usually 81-162 milligrams a day), you should continue taking the aspirin unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details.

OVERDOSE:

This medicine may be harmful if swallowed. If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose/swallowing may include: severe stomach pain, change in the amount of urine, slow/shallow breathing.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (such as blood pressure, complete blood count, liver and kidney function tests) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details. Keep all regular medical and laboratory appointments.

Lifestyle changes (such as weight loss if needed, strengthening/conditioning exercises) may help improve your flexibility and joint function. Consult your doctor for specific instructions.

MISSED DOSE:

If you are prescribed this drug on a regular schedule (not just "as needed") and you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Use your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not freeze. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist

or local waste disposal company.
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