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INFORMATION FOR THE PATIENT

Diclofenac sodium is one of a large group of non-steroidal anti-inflammatory drugs (also called NSAIDs) and is used to treat the symptoms of certain types of arthritis. It helps to relieve joint pain, swelling, stiffness and fever by reducing the production of certain substances (prostaglandins) and by helping to control inflammation. NSAIDs do not cure arthritis but they support suppression of the inflammation and the tissue-damaging effects of inflammation.

PENNSAID[®] (1.5% w/w diclofenac sodium solution) is a **TOPICAL PRODUCT** which has been prescribed by your doctor. It helps to relieve the symptoms of osteoarthritis in your knee(s): pain, stiffness and reduced function. This medicine will help you only as long as you continue to use it.

You should apply PENNSAID[®] only as directed by your doctor. Do not use more of it, do not use it more often and do not use it for a longer period of time than your doctor ordered. Using too much may increase the chance of unwanted effects, especially if you are an elderly patient.

Be sure to use PENNSAID[®] regularly as prescribed. During treatment, your doctor may decide to adjust the dosage according to your response to the medication.

Stomach upset is one of the common problems with oral NSAIDs. In clinical trials with PENNSAID[®], stomach upset was reported only occasionally. If stomach upset (indigestion, nausea, vomiting, stomach pain or diarrhea) occurs and continues, contact your doctor. PENNSAID[®] can be applied to the knee without regard to food/meal times.

Regular application of any medication to the skin can cause a localized reaction. PENNSAID[®], too, may cause dryness or other irritation of your skin, at the application site.

Do not apply any other topical medication together with PENNSAID[®].

Do not take full-strength ASA (acetylsalicylic acid), ASA-containing compounds or other drugs used to relieve symptoms of osteoarthritis while using PENNSAID[®], unless directed to do so by your physician. Consult your doctor or pharmacist before taking any other analgesic for fever, headache or other pain.

WHAT DOES PENNSAID[®] CONTAIN?

- diclofenac sodium;
- dimethyl sulfoxide;
- ethanol;
- glycerine;
- propylene glycol;
- in purified water.

ALWAYS REMEMBER:

THE RISKS OF TAKING THIS MEDICATION MUST BE WEIGHED AGAINST THE BENEFITS IT WILL HAVE.

BEFORE TAKING THIS MEDICATION TELL YOUR DOCTOR AND PHARMACISTS IF YOU:

-or a family member is allergic to or has had a reaction to PENNSAID[®] (diclofenac sodium) or other anti-inflammatory drugs (such as acetylsalicylic acid (ASA), diclofenac, diflunisal, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, mefenamic acid, piroxicam, tiaprofenic acid, tolmetin, nabumetone, or tenoxicam) manifesting itself by increased sinusitis, hives, the initiating or worsening of asthma or anaphylaxis (sudden collapse);

-or a family member has had asthma, nasal polyps, chronic sinusitis or chronic urticaria (hives);

-have a history of stomach upset, ulcer, liver, kidney or eye diseases;

-have blood or urine abnormalities;

-have high blood pressure;

-have diabetes;

-are on a special diet such as a low-sodium or low-sugar diet;

-are pregnant or intend to become pregnant while using PENNSAID[®];

-are breast feeding or intend to breast feed while using PENNSAID[®];

-are taking any other medication (either prescription or non-prescription) such as other NSAIDs, high blood pressure medication, blood thinners, corticosteroids, methotrexate, cyclosporine, lithium, phenytoin, quinolone antibacterials or probenecid;

-have active inflammatory diseases of the gastrointestinal system (*i.e.* Crohn's disease, ulcerative colitis);

-have any other medical problem(s) such as alcohol abuse, bleeding problems, kidney, liver or blood disease;

-have reactions to any other ingredients in this medication; (See "What does Pennsaid Contain");

WHILE USING THIS MEDICATION:

-tell any other doctor, dentist or pharmacist that you consult or see, that you are using this medication;

-some NSAIDs may cause drowsiness or fatigue in some people taking them. Be cautious about driving or participating in activities that require alertness if you are drowsy, dizzy or lightheaded after using this medication;

-check with your doctor if you are not getting any relief of your arthritis or if any problems develop;

-report any untoward reactions to your doctor. This is very important, as it will aid in the early detection and prevention of potential complications;

-stomach problems may be more likely to occur if you drink alcoholic beverages. Therefore, do not drink alcoholic beverages while using this medication;

-check with your doctor immediately if you experience unexpected weakness while using this medication, or if you vomit any blood or have dark or bloody stools;

-some people may become more sensitive to sunlight than they are normally. Exposure to sunlight or sunlamps, even for brief periods of time, may cause sunburn, blisters on the skin, skin rash, redness, itching or discoloration or vision changes. If you have a reaction from the sun, check with your doctor;

-check with your doctor immediately if chills, fever, muscle aches or pains, or other flu-like symptoms occur, especially if they occur shortly before, or together with, a skin rash. Very rarely, these effects may be the first signs of a serious reaction to this medication;

-YOUR REGULAR MEDICAL CHECKUPS ARE ESSENTIAL.

SIDE EFFECTS OF THIS MEDICATION:

Along with its beneficial effects, PENNSAID[®], like all other NSAIDs, may cause some undesirable reactions, especially when used for a long time or in large doses.

Elderly, frail or debilitated patients often seem to experience more frequent, or more severe, side effects with oral NSAIDs. In clinical studies with PENNSAID[®], this increase has not been observed.

Although not all of these side effects are common, when they do occur, they may require medical attention.

CHECK WITH YOUR DOCTOR IMMEDIATELY IF ANY OF THE FOLLOWING ARE NOTED:

-bloody or black tarry stools;

-shortness of breath, wheezing, any trouble in breathing or tightness in the chest;

- skin rash, hives or swelling, itching;
- vomiting or persistent indigestion, nausea, stomach pain or diarrhea;
- yellow discoloration of skin or eyes;
- any change in the amount of, or colour of, your urine (dark red or brown);
- painful or difficult urination, increased need to urinate;
- swelling of the feet or lower legs;
- malaise, fatigue, loss of appetite;
- blurred vision or any visual disturbance;
- mental confusion, depression, dizziness, lightheadedness, insomnia;
- hearing problems;
- persistent skin reactions at the application site, including dryness, tingling, itchiness or rash;
- bad breath, garlic breath or unusual body odour;
- drowsiness and headache.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor.

DOSING:

In order to obtain optimum benefit from PENNSAID[®], you should apply it regularly, exactly as your doctor has prescribed. Incomplete benefit may result if you do not follow instructions carefully.

PENNSAID[®] is intended for external use only. For best results, follow these instructions carefully:

- apply PENNSAID[®] to clean, dry skin;
- do not use under bandages or dressings;
- dispense 10 drops of PENNSAID[®] into your hand, or directly onto your knee;
- spread PENNSAID[®] evenly around front, back and sides of your knee;
- repeat this procedure until you have applied 40 drops and your knee is completely covered;
- to treat the other knee, repeat the procedure;
- allow several minutes for PENNSAID[®] to dry;
- avoid contact of synthetic fibres with skin still wet from application of PENNSAID[®];
- do not apply PENNSAID[®] to open, abraded or infected skin;
- avoid contact with your eyes or mucous membranes;
- after application, wash your hands;
- follow the same procedure 4 times, spaced evenly throughout the day;
- do not apply any other medication to the treated area;

-always use PENNSAID[®] according to your doctor's instructions;

PENNSAID[®] should not be used longer than 3 months, except on the advice of a doctor.

If you are not getting adequate relief of your symptoms, speak to your doctor before you stop using PENNSAID[®]. Although you may notice some improvement within the first few days, it may take a week, or more in some patients, to achieve maximum effect.

WHAT TO DO IF YOU MISS A DOSE:

If you miss a PENNSAID[®] treatment, do not double the next dose. Simply continue with your next scheduled application.

STORAGE:

Store at room temperature (15 – 25 °C).

PENNSAID[®] IS NOT RECOMMENDED FOR USE IN PATIENTS UNDER 18 YEARS OF AGE, SINCE SAFETY AND EFFECTIVENESS HAVE NOT BEEN ESTABLISHED IN THIS AGE GROUP.

DO NOT KEEP OUTDATED MEDICINE OR MEDICINE NO LONGER NEEDED.

KEEP OUT OF THE REACH OF CHILDREN.

THIS MEDICATION HAS BEEN PRESCRIBED FOR YOUR MEDICAL PROBLEM. DO NOT GIVE IT TO ANYONE ELSE.

IF YOU REQUIRE MORE INFORMATION ABOUT THIS DRUG, CONSULT YOUR DOCTOR OR PHARMACIST.