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Indomethacin

pronounced as (in doe meth' a sin)

IMPORTANT WARNING:

People who take nonsteroidal anti-inflammatory drugs (NSAIDs) (other than aspirin) such as indomethacin may have a higher risk of having a heart attack or a stroke than people who do not take these medications. These events may happen without warning and may cause death. This risk may be higher for people who take NSAIDs for a long time. Do not take an NSAID such as indomethacin if you have recently had a heart attack, unless directed to do so by your doctor. Tell your doctor if you or anyone in your family has or has ever had heart disease, a heart attack, or a stroke, if you smoke, and if you have or have ever had high cholesterol, high blood pressure, or diabetes. Get emergency medical help right away if you experience any of the following symptoms: chest pain, shortness of breath, weakness in one part or side of the body, or slurred speech.

If you will be undergoing a coronary artery bypass graft (CABG; a type of heart surgery), you should not take indomethacin right before or right after the surgery.

NSAIDs such as indomethacin may cause ulcers, bleeding, or holes in the stomach or intestine. These problems may develop at any time during treatment, may happen without warning symptoms, and may cause death. The risk may be higher for people who take NSAIDs for a long time, are older in age, have poor health, or drink large amounts of alcohol while you are taking indomethacin. Tell your doctor if you take any of the following medications: anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); aspirin; other NSAIDs such as diflunisal (Dolobid), ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn); oral steroids such as dexamethasone, methylprednisolone (Medrol), and prednisone(Rayos); selective serotonin reuptake inhibitors (SSRIs) such as citalopram (Celexa), fluoxetine (Prozac, Sarafem, Selfemra, in Symbyax), fluvoxamine (Luvox), paroxetine (Brisdelle, Paxil, Pexeva), and sertraline (Zoloft); or serotonin norepinephrine reuptake inhibitors (SNRIs) such as desvenlafaxine (Khedezla, Pristiq), duloxetine (Cymbalta), and venlafaxine (Effexor XR). Also tell your doctor if you have or have ever had ulcers or bleeding in your stomach or intestines or other bleeding disorders. If you experience any of the following symptoms, stop taking indomethacin and call your doctor: stomach pain, heartburn, vomit that is bloody or looks like coffee grounds, blood in the stool, or black and tarry stools.

Keep all appointments with your doctor and the laboratory. Your doctor will monitor your symptoms carefully and will probably order certain tests to check your body's response to indomethacin. Be sure to tell your doctor how you are feeling so that your doctor can prescribe the right amount of medication to treat your condition with the lowest risk of serious side effects.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with indomethacin and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (http://www.fda.gov/Drugs [http://www.fda.gov/Drugs]) or the manufacturer's website to obtain the Medication Guide.

Why is this medication prescribed?

Indomethacin is used to relieve moderate to severe pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints), rheumatoid arthritis (arthritis caused by swelling of the lining of the joints), and ankylosing spondylitis (arthritis that mainly affects the spine). Indomethacin is also used to treat pain in the shoulder caused by bursitis (inflammation of a fluid-filled sac in the shoulder joint) and tendinitis (inflammation of the tissue that connects muscle to bone). Indomethacin immediate-release capsules, suspension (liquid) and suppositories are also used to treat acute gouty arthritis (attacks of severe joint pain and swelling caused by a build-up of certain substances in the joints). Indomethacin is in a class of medications called NSAIDs. It works by stopping the body's production of a substance that causes pain, fever, and inflammation.

How should this medicine be used?

Indomethacin comes as a capsule, an extended-release (long-acting) capsule, and a suspension to take by mouth and as a suppository to be used rectally. Indomethacin capsules and liquid usually are taken two to four times a day. Indomethacin suppositories usually are used two to four times daily. Extendedrelease capsules are usually taken one or two times a day. Indomethacin capsules, extended-release capsules, and suspension should be taken with food, immediately after meals, or with antacids. Take indomethacin at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take indomethacin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the extended-release capsules whole; do not split, chew, or crush them.

Shake the suspension well before each use to mix the medication evenly.

Your doctor may change the dose of your medication during your treatment. In some cases, your doctor may start you on a low dose of indomethacin and gradually increase your dose, not more often than once a week. In other cases, your doctor may start you on an average dose of indomethacin and decrease your dose once your symptoms are controlled. Follow these directions carefully and ask your doctor or pharmacist if you have any questions.

To use indomethacin suppositories, follow these steps:

- 1. Remove the wrapper.
- 2. Dip the tip of the suppository in water.
- 3. Lie down on your left side and raise your right knee to your chest. (A left-handed person should lie on the right side and raise the left knee.)
- 4. Using your finger, insert the suppository about 1 inch (2.5 centimeters) into the rectum. Hold it in place for a few moments.
- 5. Stand up after about 15 minutes. Wash your hands thoroughly and resume your normal activities.
- 6. You should try to keep the suppository in place and avoid having a bowel movement for 1 hour after you insert the suppository.

Other uses for this medicine

Indomethacin is also sometimes used to relieve fever, pain, and inflammation caused by many types of conditions or injuries, to reduce the amount of calcium in the blood, and to treat a certain type of low blood pressure. Talk to your doctor about the risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking indomethacin,

- tell your doctor and pharmacist if you are allergic to indomethacin, aspirin or other NSAIDs such as ibuprofen (Advil, Motrin) and naproxen (Aleve, Naprosyn), any other medications, or any of the inactive ingredients in indomethacin capsules, suspension, extended release capsules, or suppositories. Ask your pharmacist for a list of the inactive ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention the medications listed in the IMPORTANT WARNING section and any of the following: angiotensinconverting enzyme (ACE) inhibitors such as benazepril (Lotensin, in Lotrel), captopril, enalapril (Vasotec, in Vaseretic), fosinopril, lisinopril (in Zestoretic), moexipril (Univasc, in Uniretic), perindopril (Aceon, in Prestalia), quinapril (Accupril, in Accuretic, in Quinaretic), ramipril (Altace), and trandolapril (Mavik, in Tarka); angiotensin receptor blockers such as candesartan (Atacand, in Atacand HCT), eprosartan (Teveten), irbesartan (Avapro, in Avalide), losartan (Cozaar. in Hyzaar), olmesartan (Benicar, in Azor, in Benicar HCT, in Tribenzor), telmisartan (Micardis, in Micardis HCT, in

Twynsta), and valsartan (in Diovan HCT, in Exforge); beta blockers such as atenolol (Tenormin, in Tenoretic), labetalol (Trandate), metoprolol (Lopressor, Toprol XL, in Dutoprol), nadolol (Corgard, in Corzide), and propranolol (Hemangeol, Inderal, Innopran); cyclosporine (Gengraf, Neoral, Sandimmune); digoxin (Lanoxin); diuretics ('water pills') such as triamterene (Dyrenium, in Dyazide); lithium (Lithobid); methotrexate (Otrexup, Rasuvo, Trexall); phenytoin (Dilantin, Phenytek); and probenecid (Probalan, in Col-Probenecid). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor if you have or have ever had asthma, especially if you also have frequent stuffed or runny nose or nasal polyps (swelling of the lining of the nose); heart failure; seizures; Parkinson's disease; depression or mental illness; or liver or kidney disease. If you will be using indomethacin suppositories, also tell your doctor if you have or have ever had proctitis (inflammation of the rectum) or have or have recently had rectal bleeding.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy; you plan to become pregnant; or you are breastfeeding. If you become pregnant while taking indomethacin, call your doctor.
- talk to your doctor about the risks and benefits of taking indomethacin if you are 65 years of age or older. Older adults should not usually take indomethacin because it is not as safe as other medications that can be used to treat the same condition.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking indomethacin.
- you should know that this medication may make you drowsy. Do not drive a car or operate machinery until you know how this medication affects you.
- talk to your doctor about the safe use of alcohol during your treatment with indomethacin. Alcohol can make the side effects of indomethacin worse.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Indomethacin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- dizziness

- vomiting
- diarrhea
- constipation
- irritation of the rectum
- constant feeling of the need to empty the bowel
- ringing in the ears

Some side effects can be serious. If you experience any of the following symptoms or those mentioned in the IMPORTANT WARNING section, call your doctor immediately. Do not take any more indomethacin until you speak to your doctor.

- unexplained weight gain
- · shortness of breath or difficulty breathing
- swelling in the abdomen, ankles, feet, or legs
- fever
- blisters
- rash
- itching
- hives
- swelling of the eyes, face, tongue, lips, throat, or hands
- · difficulty breathing or swallowing
- hoarseness
- pale skin
- fast heartbeat
- excessive tiredness
- unusual bleeding or bruising
- lack of energy
- nausea
- loss of appetite
- pain in the upper right part of the stomach
- flu-like symptoms
- yellowing of the skin or eyes

- cloudy, discolored, or bloody urine
- back pain
- difficult or painful urination
- blurred vision or other problems with sight

Indomethacin may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (http://www.fda.gov/Safety/MedWatch]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (http://goo.gl/c4Rm4p [http://goo.gl /c4Rm4p]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. http://www.upandaway.org [http://www.upandaway.org]

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include the following:

- nausea
- vomiting
- headache
- dizziness

- confusion
- extreme tiredness
- feeling of numbness, pricking, burning, or creeping on the skin
- seizures

What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are taking indomethacin.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-thecounter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Indocin ®
- Tivorbex ®

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