Read this medicine information sheet carefully each time you get this medicine filled. You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

GENERIC NAME: **LIDOCAINE CREAM**

PRONUNCIATION (LYE doe kane)

BRAND NAMES: US L-M-X4; LidaMantle.

WHAT IS THIS DRUG USED FOR? It is used to manage pain. It is used to treat signs of hemorrhoids or rectal irritation. It may be given to you for other reasons. Talk with the doctor.

WHAT DO I NEED TO TELL MY DOCTOR BEFORE I TAKE THIS DRUG? If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had. If there is an infection where this drug will be used. If you have broken skin or open wounds where the drug will be used. If you have swollen skin, numbness, or are not able to feel pain where the drug will be used. If a large area needs to be treated. This is not a list of all drugs or health problems that interact with this drug. Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

WHAT ARE SOME THINGS I NEED TO KNOW OR DO WHILE I TAKE THIS DRUG? Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists. A severe blood problem called methemoglobinemia has happened with drugs like this one. The risk may be raised in people who have glucose-6-phosphate dehydrogenase (G6PD) deficiency, heart problems, or lung problems. The risk may also be raised while taking certain other drugs and in infants younger than 6 months of age. Tell your doctor if you have ever had methemoglobinemia. Talk with your doctor before you use other drugs or products on your skin. This includes soaps. Do not use this drug for longer than you were told by your doctor. Do not scratch or rub the skin while it is numb. Do not let it get very hot or very cold. Do not put on cuts, scrapes, or damaged skin unless the doctor tells you to. Avoid use of heat sources (such as sunlamps, tanning beds, heating pads, electric blankets, heat lamps, saunas, hot tubs, heated waterbeds). Avoid long, hot baths or sunbathing. Your temperature may rise and cause too much drug to pass into your body. This drug may cause harm if swallowed. If this drug is swallowed, call a doctor or poison control center right away. Different brands of this drug may be for use in different ages of children. Talk with the doctor before giving this drug to a child. If the patient is a child, use this drug with care. The risk of some side effects may be higher in children. If you are 65 or older, use this drug with care. You could have more side effects. Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

WHAT ARE SOME SIDE EFFECTS THAT I NEED TO CALL MY DOCTOR ABOUT RIGHT AWAY? WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect: For all uses of this drug: Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat. Signs of too much acid in the blood (acidosis) like confusion; fast breathing; fast heartbeat; a heartbeat that does not feel normal; very bad stomach pain, upset stomach, or throwing up; feeling very sleepy; shortness of breath; or feeling very tired or weak. Signs of

methemoglobinemia like a blue or gray color of the lips, nails, or skin; a heartbeat that does not feel normal; seizures; severe dizziness or passing out; severe headache; feeling very sleepy; feeling tired or weak; or shortness of breath. This effect is rare but may be deadly if it happens. Signs of skin infection like oozing, heat, swelling, redness, or pain. Trouble breathing, slow breathing, or shallow breathing. Very bad numbness and tingling. Feeling lightheaded, sleepy, confused, or having blurred eyesight. Seizures. Change in eyesight. Feeling nervous and excitable. Dizziness or passing out. Ringing in ears. Upset stomach or throwing up. Feeling hot or cold. Shakiness. Twitching. Slow heartbeat. Chest pain. All rectal products: Bleeding from rectum or rectal pain.

WHAT ARE SOME OTHER SIDE EFFECTS OF THIS DRUG? All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away: Irritation where this drug was used. Swelling. Redness. Change in color of skin. These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

HOW IS THIS DRUG BEST TAKEN? Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely. All rectal products: Wash your hands before and after use. Put on clean, dry skin. Put this drug on as you have been told by the doctor or on the package labeling. All skin products: Do not take this drug by mouth. Use on your skin only. Keep out of your mouth, nose, and eyes (may burn). If you get this drug in any of these areas, rinse well with water. Wash your hands before and after use. If your hand is the treated area, do not wash your hand after use. Clean affected part before use. Make sure to dry well. Put on clean, dry, healthy skin. Do not use coverings (bandages, dressings) unless told to do so by the doctor.

WHAT DO I DO IF I MISS A DOSE? If you use this drug on a regular basis, use a missed dose as soon as you think about it. If it is close to the time for your next dose, skip the missed dose and go back to your normal time. Do not put on 2 doses at the same time or extra doses. Many times this drug is used on an as needed basis. Do not use more often than told by the doctor.

HOW DO I STORE AND/OR THROW OUT THIS DRUG? Store at room temperature. Do not freeze. Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets. Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

GENERAL DRUG FACTS If your symptoms or health problems do not get better or if they become worse, call your doctor. Do not share your drugs with others and do not take anyone else's drugs. Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider. If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

CONSUMER INFORMATION USE AND DISCLAIMER This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient.