







USES

This medication is used in combination with other drugs in the treatment of advanced cancer of the colon or rectum (metastatic colorectal cancer).

HOW TO USE

This medication is administered by infusion into a vein over at least 2 hours by a health care professional. It is given as one dose every 2 weeks, along with other drugs (i.e., 5-fluorouracil and leucovorin). This cycle is repeated every 2 weeks. The dose and frequency is based on your blood count and response to previous doses. This medication comes with a patient information leaflet. Read it carefully. Ask your doctor, nurse or pharmacist any questions that you may have about this medication. Follow all instructions for proper mixing and dilution with correct IV fluids. Follow all safety precautions. Consult your pharmacist for details. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Tell your doctor or nurse immediately if you experience pain, burning or redness at the place where injected. If this medication contacts your skin, immediately and completely wash skin with soap and water. If this medication contacts your eyes, nose, or mouth immediately and completely flush the area with water. If more that one drug is to be given through the same IV line, the IV line should be flushed before and after use with a dextrose solution (5% Dextrose in Water). Do not give other IV drugs together with this medication without flushing the IV line.

SIDE EFFECTS

Nausea and vomiting may be severe in some patients. Medication may be given prior to and after therapy to help reduce this effect. Pain, diarrhea, constipation, fatigue, headaches, dizziness, heartburn, change in taste, hiccups, runny nose, trouble sleeping, or hair loss may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly. Tell your doctor immediately if any of these serious side effects occur: pain/burning/redness at the injection site, nose bleeds, loss of appetite, mouth sores, unusual bruising or bleeding, depression, fast or irregular heartbeat. Tell your doctor immediately if any of these unlikely but serious side effects occur: dry cough, shortness of breath, decreased urination/thirst/dry mouth (dehydration), muscle cramps, weakness, groin or calf pain, sudden severe headache, chest pain. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: black stools, "coffee-ground" - appearing vomit, persistent stomach/abdominal pain. Oxaliplatin can affect how your nerves work (peripheral neuropathy). Tell your doctor promptly if you develop the following symptoms: sensitivity to cold temperature and cold objects, trouble breathing/swallowing, jaw tightness, strange feeling in your tongue, eye pain, chest pressure, numbness or tingling of hands or feet. You may lessen these types of nerve problems by avoiding cold drinks, use of ice, and covering skin prior to exposure to cold temperature. An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing. If you notice other effects not listed above, contact your doctor or pharmacist.

PRECAUTIONS

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: allergy to platinum products (e.g., cisplatin, carboplatin). Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney problems, pre-existing blood disorders, bone marrow disease, nerve disorders, any other allergies. This medication can lower the body's ability to fight an infection. Notify your doctor promptly if you develop any signs of an infections such as fever, chills or persistent sore throat. Do not have immunizations/vaccinations without the consent of your doctor and avoid contact with people who have recently received oral polio vaccine. Use caution with sharp objects like safety razors or nail cutters and avoid activities such as contact sports to lower the chance of getting cut, bruised, or injured. Caution is advised when using this drug in the elderly because they may be more sensitive to the side effects, especially diarrhea, dehydration, loss of potassium (hypokalemia), and fatigue. This medication must not be used during pregnancy. If you become pregnant or think you may be pregnant, inform your doctor immediately. It is recommended that women of childbearing age use effective birth control measures while taking this drug since oxaliplatin may cause fetal harm. It is not known if oxaliplatin passes into breast milk. Breast-feeding is not recommended while using this drug.

DRUG INTERACTIONS

Before using this medication, tell your doctor or pharmacist of all prescription and nonprescription products you may use, especially of: aminoglycosides (e.g., gentamicin, amikacin), amphotericin B, cyclosporine, non-steroidal antiinflammatory drugs (e.g., ibuprofen), tacrolimus, vancomycin. Do not start or stop any medicine without doctor or pharmacist approval.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US national poison hotline at 1-800-222-1222. Canadian residents should call their local poison control center directly. Symptoms of overdose may include easy bruising or bleeding, persistent sore throat or fever, fatigue, severe nausea and vomiting, diarrhea, chest pain, shortness of breath, wheezing, very slow heartbeat, or numbness or tingling in arms, hands, legs, or feet.

MISSED DOSE

It is important that each dose be used as scheduled. If you miss a dose, contact your doctor who will help establish a new dose schedule. Do not "double-up" the dose to catch up.

STORAGE

Store the unmixed vials at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 56 and 86 degrees F (15-30 degrees C) is permitted. Once prepared, this medication is stable for only 6 hours at room temperature (59-86 degrees F or 15-30 degrees C) or up to 24 hours when refrigerated between 36 and 46 degrees F (2-8 degrees C). Check the expiration date on the label and properly discard of any unused medication after that time. Keep all medicines away from children and pets.

WARNING: Oxaliplatin may very rarely cause severe (sometimes fatal) allergic reactions during the infusion. Notify your doctor immediately if you experience signs of an allergic reaction such as rash, itching skin, breathing difficulties, or dizziness.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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