OXDERYS™
(doxorubicin hydrochloride injection)

AVYXA

Ordering Information

To order OXDERYS™ (doxorubicin hydrochloride injection), please contact one of the authorized specialty distributors below:



40 mg/20 mL (2 mg/mL)
NDC: 83831-0161-20



160 mg/80 mL (2 mg/mL)
NDC: 83831-0162-80

Institutions/Hospitals	40 mg/20 mL	160 mg/80 mL
[ASD Healthcare (Cencora)]	10314917	10314968
[Cardinal Health Specialty]	6180459	6180467
[McKesson Plasma & Biologics]	3115201	3115219
Physician Offices	**40 mg/20 mL**	**160 mg/80 mL**
[BioCare]	1004679	1004678
[Cardinal Health Specialty]	6180459	6180467
[McKesson Specialty]	5024060	5024061
[Oncology Supply (Cencora)]	10315010	10314933

Highlights[1]

- Supplied in 40 mg/20 mL and 160 mg/80 mL multi-dose vials
- No reconstitution required and ready-to-dilute solution
- Ready to add to intravenous infusion solution with different options:
  - 0.9% Sodium Chloride Injection, USP
  - 5% Dextrose Injection, USP
- Diluted infusion solution is stable for 24 hours at room temperature up to 25°C (77°F) or refrigerated at 2°C to 8°C (36°F to 46°F)
- Partially used vials are stable for up to 28 days when stored in the original carton refrigerated at 2°C to 8°C (36°F to 46°F)

J-CODE

J9999

Unique J-Code Expected July 2027

Please see Important Safety Information including **Boxed Warning**, on page 2-3 and full Prescribing Information for OXDERYS.

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

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INDICATIONS

Adjuvant Breast Cancer

OXDERYS™ is indicated as a component of multi-agent adjuvant chemotherapy for treatment of adults with axillary lymph node involvement following resection of primary breast cancer.

Other Cancers

OXDERYS is indicated for the treatment of

- acute lymphoblastic leukemia
- acute myeloblastic leukemia
- Hodgkin lymphoma
- non-Hodgkin lymphoma (NHL)
- metastatic breast cancer
- metastatic Wilms' tumor
- metastatic neuroblastoma
- metastatic soft tissue sarcoma
- metastatic bone sarcoma
- metastatic ovarian carcinoma
- metastatic transitional cell bladder carcinoma
- metastatic thyroid carcinoma
- metastatic gastric carcinoma
- metastatic bronchogenic carcinoma

IMPORTANT SAFETY INFORMATION

WARNING: CARDIOMYOPATHY, SECONDARY MALIGNANCIES, EXTRAVASATION AND TISSUE NECROSIS, and SEVERE MYELOSUPPRESSION

- **Cardiomyopathy: Myocardial damage, including acute left ventricular failure, can occur with OXDERYS. The risk of cardiomyopathy is proportional to the cumulative exposure with incidence rates from 1% to 20% for cumulative doses ranging from 300 mg/m² to 500 mg/m² when OXDERYS is administered every 3 weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess left ventricular ejection fraction (LVEF) before and regularly during and after treatment with OXDERYS.**
- **Secondary Malignancies: Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including OXDERYS.**
- **Extravasation and Tissue Necrosis: Extravasation of OXDERYS can result in severe local tissue injury and necrosis requiring wide excision of the affected area and skin grafting. Immediately terminate the drug and apply ice to the affected area.**
- **Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur.**

CONTRAINDICATIONS

OXDERYS is contraindicated in patients with:

- Severe myocardial insufficiency
- Recent (occurring within the past 4-6 weeks) myocardial infarction
- Severe persistent drug-induced myelosuppression
- Severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin level greater than 5 mg/dL)
- Severe hypersensitivity reaction to doxorubicin hydrochloride, including anaphylaxis

WARNINGS AND PRECAUTIONS

Cardiomyopathy and Arrhythmias

Cardiomyopathy

OXDERYS can result in myocardial damage, including acute left ventricular failure. The risk of cardiomyopathy is generally proportional to the cumulative exposure. Include prior doses of other anthracyclines or anthracenediones in calculations of total cumulative dosage for OXDERYS. Cardiomyopathy may develop during treatment or up to several years after completion of treatment and can include decrease in LVEF and signs and symptoms of congestive heart failure (CHF). The probability of developing cardiomyopathy is estimated to be 1 to 2% at a total cumulative dose of 300 mg/m² of doxorubicin hydrochloride, 3 to 5% at a dose of 400 mg/m², 5 to 8% at a dose of 450 mg/m², and 6 to 20% at a dose of 500 mg/m², when doxorubicin hydrochloride is administered every 3 weeks. There is an additive or potentially synergistic increase in the risk of cardiomyopathy in patients who have received radiotherapy to the mediastinum or concomitant therapy with other known cardiotoxic agents, such as cyclophosphamide and trastuzumab.

Pericarditis and myocarditis have also been reported during or following doxorubicin hydrochloride treatment.

Assess left ventricular cardiac function (e.g., MUGA or echocardiogram) prior to initiation of OXDERYS, during treatment to detect acute changes, and after treatment to detect delayed cardiotoxicity. Increase the frequency of assessments as the cumulative dose exceeds 300 mg/m². Use the same method of assessment of LVEF at all time points. Discontinue OXDERYS in patients who develop signs or symptoms of cardiomyopathy.

Consider the use of dexrazoxane to reduce the incidence and severity of cardiomyopathy due to OXDERYS administration in patients who have received a cumulative OXDERYS dose of 300 mg/m² and who will continue to receive OXDERYS.

Arrhythmias

OXDERYS can result in arrhythmias, including life-threatening arrhythmias, during or within a few hours after OXDERYS administration and at any time point during treatment. Tachyarrhythmias, including sinus tachycardia, premature ventricular contractions, and ventricular tachycardia, as well as bradycardia, can occur. Electrocardiographic changes, including non-specific ST-T wave changes, atrioventricular and bundle-branch block can also occur. These electrocardiographic changes may be transient and self-limited and may not require a dosage modification of OXDERYS.

Secondary Malignancies

The risk of developing secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) is increased following treatment with OXDERYS. Cumulative incidences ranged from 0.2% at five years to 1.5% at 10 years in two separate trials involving the adjuvant treatment of women with breast cancer. These leukemias generally occur within 1 to 3 years of treatment.

Extravasation and Tissue Necrosis

Extravasation of OXDERYS can cause severe local tissue injury manifesting as blistering, ulceration, and necrosis requiring wide excision of the affected area and skin grafting.

Extravasation should be considered if a patient experiences a burning or stinging sensation or shows other evidence indicating peri-venous infiltration or extravasation; however, extravasation may be present in patients who do not experience a stinging or burning sensation or when blood return is present on aspiration of the infusion needle.

When given via a peripheral venous line, infuse OXDERYS over 10 minutes or less to minimize the risk of thrombosis or perivenous extravasation.

If extravasation is suspected, immediately discontinue the intravenous injection or continuous intravenous infusion. Apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days. In adults, if appropriate, administer dexrazoxane at the site of extravasation as soon as possible and within the first 6 hours after extravasation.

Severe Myelosuppression

OXDERYS can cause myelosuppression. In Study 1, the incidence of severe myelosuppression was: grade 4 leukopenia (0.3%), grade 3 leukopenia (3%), and grade 4 thrombocytopenia (0.1%). A dose-dependent, reversible neutropenia is the predominant manifestation of myelosuppression from doxorubicin hydrochloride. When OXDERYS is administered every 21 days, the neutrophil count reaches its nadir 10 to 14 days after administration with recovery usually occurring by day 21.

Obtain complete blood counts prior to each treatment and carefully monitor patients during treatment for possible clinical complications due to myelosuppression. Delay next dose of OXDERYS if severe myelosuppression has not improved. Consider dose reduction for patients with prolonged myelosuppression based on severity of reaction.

Tumor Lysis Syndrome

OXDERYS can induce tumor lysis syndrome in patients with rapidly growing tumors. Evaluate blood uric acid levels, potassium, calcium, phosphate, and creatinine after initial treatment. Hydration, urine alkalinization, and prophylaxis with allopurinol to prevent hyperuricemia may minimize potential complications of tumor lysis syndrome.

Potentiation of Radiation Toxicity and Radiation Recall

OXDERYS can increase radiation-induced toxicity to the myocardium, mucosa, skin, and liver. Radiation recall, including but not limited to cutaneous and pulmonary toxicity, can occur in patients who receive OXDERYS after prior radiation therapy.

Embryo-Fetal Toxicity

OXDERYS can cause fetal harm when administered to a pregnant woman; avoid the use of OXDERYS during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of doxorubicin

Please see Important Safety Information including **Boxed Warning**, on page 2-3 and full Prescribing Information for OXDERYS.

IMPORTANT SAFETY INFORMATION (continued)

hydrochloride during the 2nd and 3rd trimesters. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OXDERYS and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with OXDERYS and for 3 months after the last dose. Advise males with pregnant partners to use condoms during treatment with OXDERYS and for at least 10 days after the last dose.

ADVERSE REACTIONS

The most common (>10%) adverse reactions are alopecia, nausea and vomiting.

DRUG INTERACTIONS

Effect of Other Drugs on OXDERYS

Inhibitors of CYP3A4, CYP2D6, and P-gp

- Avoid concomitant use of OXDERYS with inhibitors of CYP3A4, CYP2D6, or P-gp. Concomitant use of doxorubicin hydrochloride with inhibitors of CYP3A4, CYP2D6, or P- glycoprotein (P-gp), increased concentrations of doxorubicin, which may increase the incidence and severity of adverse reactions of OXDERYS.

Inducers of CYP3A4, CYP2D6, or P-gp

- Avoid concomitant use of OXDERYS with inducers of CYP3A4, CYP2D6, or P-gp. Concomitant use of doxorubicin hydrochloride with inducers of CYP3A4, CYP2D6, or P-gp may decrease the concentration of doxorubicin.

Paclitaxel

- Administer OXDERYS prior to paclitaxel if used concomitantly. Paclitaxel, when given prior to doxorubicin hydrochloride, increases the plasma concentrations of doxorubicin and its metabolites.

Concomitant Use of Trastuzumab

Avoid concomitant administration of OXDERYS and trastuzumab. Concomitant use of trastuzumab and doxorubicin hydrochloride results in an increased risk of cardiac dysfunction.

Patients receiving doxorubicin after stopping treatment with trastuzumab may also be at an increased risk of developing cardiotoxicity. Trastuzumab may persist in the circulation for up to 7 months. Therefore, avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab when possible. If anthracyclines are used before this time, carefully monitor cardiac function.

Concomitant Use of Dexrazoxane

Do not administer dexrazoxane as a cardioprotectant at the initiation of OXDERYS-containing chemotherapy regimens.

Concomitant Use of 6-Mercaptopurine

OXDERYS may potentiate 6-mercaptopurine-induced hepatotoxicity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Doxorubicin hydrochloride injection can cause fetal harm when administered to a pregnant woman. Avoid the use of OXDERYS during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of doxorubicin hydrochloride during the 2nd and 3rd trimesters. Advise pregnant women of the potential risk to a fetus.

Lactation

Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with OXDERYS and for 10 days after the last dose.

Females and Males of Reproductive Potential

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating OXDERYS.

Contraception

OXDERYS can cause fetal harm when administered to pregnant women. Advise female patients of reproductive potential to use effective contraception during treatment with OXDERYS and for 6 months after the last dose.

OXDERYS may damage spermatozoa and testicular tissue, resulting in possible genetic fetal abnormalities. Due to the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with OXDERYS and for 3 months after the last dose. Males with pregnant partners should use condoms during treatment and for at least 10 days after the last dose.

Infertility

In females of reproductive potential, OXDERYS may cause infertility and result in amenorrhea. Premature menopause can occur. Recovery of menses and ovulation is related to age at treatment.

OXDERYS may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men. This may occur several years after the end of therapy.

Pediatric Use

Based on postmarketing reports, pediatric patients treated with doxorubicin hydrochloride are at risk for developing late cardiovascular dysfunction. Risk factors include young age at treatment (especially < 5 years), high cumulative doses and receipt of combined modality therapy. Long-term periodic cardiovascular monitoring is recommended for all pediatric patients who have received doxorubicin hydrochloride. OXDERYS, as a component of intensive chemotherapy regimens administered to pediatric patients, may contribute to prepubertal growth failure and may also contribute to gonadal impairment, which is usually temporary.

There are no recommended dose adjustments based on age. Doxorubicin clearance was increased in patients aged 2 years to 20 years as compared to adults, while doxorubicin clearance was similar in infants less than 2 years as compared to adults.

Geriatric Use

Clinical experience in patients who were 65 years of age and older who received doxorubicin hydrochloride-based chemotherapy regimens for metastatic breast cancer showed no overall differences in safety and effectiveness compared with younger patients.

Hepatic Impairment

The clearance of doxorubicin was reduced in patients with elevated serum total bilirubin levels. OXDERYS is contraindicated in patients with severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin levels greater than 5 mg/dL). Reduce the dose of OXDERYS in patients with serum total bilirubin levels greater than 1.2 mg/dL.

DOSAGE AND ADMINISTRATION

OXDERYS is a hazardous drug. Follow applicable special handling and disposal procedures.

Decrease the rate of infusion if erythematous streaking along the vein proximal to the site of infusion or facial flushing occur.

Management of Suspected Extravasation

Immediately discontinue OXDERYS for burning or stinging sensation or other evidence indicating peri-venous infiltration or extravasation. Manage confirmed or suspected extravasation as follows:

- Do not remove the needle until attempts are made to aspirate extravasated fluid.
- Do not flush the line.
- Avoid applying pressure to the site.
- Apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days.
- If the extravasation is in an extremity, elevate the extremity.
- In adults, consider administration of dexrazoxane.

Management of Contact with Skin or Eyes

Treat accidental contact with the skin or eyes immediately by copious lavage with water, or soap and water, or sodium bicarbonate solution. Do not abrade the skin by using a scrub brush. Seek medical attention.

Incompatibility with Other Drugs

Do not admix OXDERYS with other drugs. If OXDERYS is mixed with heparin or fluorouracil, a precipitate may form. Avoid contact with alkaline solutions which can lead to hydrolysis of doxorubicin hydrochloride.

Please see OXDERYS full Prescribing Information, including BOXED WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact AVYXA Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference: 1. AVYXA Pharma, LLC. OXDERYS™ (doxorubicin hydrochloride injection). Prescribing information. Revised 11/2026.

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AVYXA Pharma, LLC offers resources to help your patients start and stay on prescribed therapy. We are dedicated to providing your patients with ongoing support to help them access AVYXA Pharma, LLC medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

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