

DaunoXome[®] (daunorubicin citrate liposome injection) Media Fact Sheet

Key facts

- DaunoXome[®] (daunorubicin citrate liposome injection) is a chemotherapy agent, which belongs to a class of drugs known as anthracyclines.
- DaunoXome[®] has been approved in the United States since 1996 for advanced HIV-associated Kaposi's sarcoma (KS).¹
- Anthracyclines work by attacking cancer cells and interfering with DNA production, which stops cancer cells from multiplying.²
- DaunoXome[®] has a different delivery system compared with conventional anthracyclines; it has a type of coating and particle size, which enables it to effectively target malignant tumors.^{1,3,4}
- DaunoXome[®] is owned and distributed by Galen. Galen is a global pharmaceutical company headquartered in Northern Ireland, UK, which has recently acquired DaunoXome[®] from Gilead Sciences, Inc. Galen US, Inc., a wholly owned subsidiary of Galen Ltd., will market DaunoXome[®] in the United States.

What is DaunoXome[®] (daunorubicin citrate liposome injection)?

- DaunoXome[®] is a chemotherapy agent, which belongs to a class of drugs known as anthracyclines.
- DaunoXome[®] has been approved in the United States since 1996 for advanced HIV-associated Kaposi's sarcoma (KS).¹
- Since its launch in the United States in 1996, thousands of patients have been treated with DaunoXome[®] worldwide.⁵

How does DaunoXome[®] (daunorubicin citrate liposome injection) work?

- Anthracyclines work by attacking cancer cells and interfering with DNA production, which stops cancer cells from multiplying.²
- DaunoXome[®] has a different delivery system compared with conventional anthracyclines; it has a type of coating and particle size, which enables it to effectively target malignant tumors.^{1,3,4}

What does DaunoXome[®] (daunorubicin citrate liposome injection) treat?

- DaunoXome[®] has been approved for treatment of advanced HIV-associated KS for more than 15 years. KS is a type of cancer that affects both the skin and organs inside the body, such as the lungs, liver and digestive tract, in patients living with active HIV.^{6,7}

What is the safety profile of DaunoXome[®] (daunorubicin citrate liposome injection)?

- DaunoXome[®] has a safety profile similar to other anthracycline chemotherapy agents.⁸

Where is DaunoXome[®] (daunorubicin citrate liposome injection) manufactured?

- DaunoXome[®] is manufactured in San Dimas, California, by Gilead Sciences, Inc. and is owned and distributed by Galen.

DaunoXome[®] will be made available through wholesalers in the United States.

DaunoXome[®] is a prescription drug. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 (1-800-332-1088). If you have a medical information inquiry or wish to report a side effect relating to DaunoXome[®] to the company, call 1-855-DAUNOXOME (1-855-328-669663).

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- Cardiac function should be monitored regularly in patients receiving DaunoXome[®] (daunorubicin citrate liposome injection) because of the potential risk for cardiac toxicity and congestive heart failure. Cardiac monitoring is advised especially in those patients who have received prior anthracyclines or who have pre-existing cardiac disease or who have had prior radiotherapy encompassing the heart.
- Severe myelosuppression may occur.
- DaunoXome[®] should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents.
- Dosage should be reduced in patients with impaired hepatic function.
- A triad of back pain, flushing, and chest tightness has been reported in 13.8% of the patients (16/116) treated with DaunoXome[®] in the Phase III clinical trial, and in 2.7% of treatment cycles (27/994). This triad generally occurs during the first five minutes of the infusion, subsides with interruption of the infusion, and generally does not recur if the infusion is then resumed at a slower rate.

Contraindications

- Therapy with DaunoXome[®] is contraindicated in patients who have experienced a serious hypersensitivity reaction to previous doses of DaunoXome[®] or to any of its constituents.

Additional Safety Information

- The primary toxicity of DaunoXome[®] is myelosuppression. Careful hematologic monitoring is required and since patients with HIV infection are immunocompromised, patients must be observed closely for evidence of intercurrent or opportunistic infections.
- Special attention must be given to the potential cardiac toxicity of DaunoXome[®]. Patients who have received prior therapy with anthracyclines (doxorubicin > 300mg/m² or equivalent), have pre-existing cardiac disease, or have received previous radiotherapy encompassing the heart may be less “cardiac” tolerant to treatment with DaunoXome[®]. Monitoring of LVEF at cumulative DaunoXome[®] doses should occur prior to therapy and every 160mg/m² of DaunoXome[®].
- Daunorubicin has been associated with local tissue necrosis at the site of drug extravasation. Although no such local tissue necrosis has been observed with DaunoXome[®], care should be taken to ensure that there is no extravasation of drug when DaunoXome[®] is administered.

- The safety and effectiveness of DaunoXome[®] in pediatric and elderly patients have not been established.
- Safety has not been established in patients with pre-existing hepatic or renal dysfunction. Based on experience with conventional daunorubicin hydrochloride, it is recommended that the dosage of DaunoXome[®] should be reduced in patients with impaired hepatic or renal function; refer to the full Package Insert for details.
- Pregnancy Category D: DaunoXome[®] can cause fetal harm when administered to a pregnant woman.
- If DaunoXome[®] is used during pregnancy, or if the patient becomes pregnant while being treated with DaunoXome[®], the patient must be warned of the potential hazard to the fetus. Patients should be advised to avoid becoming pregnant while being treated with DaunoXome[®].

Indication

- DaunoXome[®] is indicated as a first line cytotoxic therapy for advanced HIV-associated Kaposi's sarcoma. DaunoXome[®] is not recommended in patients with less than advanced HIV-related Kaposi's sarcoma.

References

1. DaunoXome[®] (daunorubicin citrate liposome injection) US Package Insert. Revised December 2011.
2. Brunton LL, Chabner BA, Knollmann BC, editors. *Goodman & Gilman's The Pharmacological Basis of Therapeutics*, 12th edition. New York, Chicago, San Francisco, McGraw-Hill. 2011: 1671.
3. Forssen EA *et al.* Fluorescence Imaging Studies for the Disposition of Daunorubicin Liposomes (DaunoXome) within Tumor Tissue. *Cancer Res* 1996; 56: 2066-2075.
4. Forssen EA. The design and development of DaunoXome for solid tumour targeting in vivo. *Advanced Drug Delivery Reviews* 1997; 24: 133-150.
5. Data on file 2, Galen Ltd.
6. National AIDS Education and Training Centers National Resource Center. http://www.aids-ed.org/aidsetc?page=cg-620_kaposi_sarcoma. Accessed February 2012.
7. American Cancer Society. What is Kaposi Sarcoma? <http://www.cancer.org/Cancer/KaposiSarcoma/DetailedGuide/kaposi-sarcoma-what-is-kaposi-sarcoma>. Accessed February 2012.
8. Data on file 3, Galen Ltd.

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