HIV-associated Kaposi’s sarcoma (KS) Media Fact Sheet

Key facts

- 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.1,2
- For the treatment of KS, highly active antiretroviral therapy (HAART) is used to slow the progression of AIDS. If the disease advances or is poorly controlled, chemotherapy treatment may be added into the regimen.3,4
- DaunoXome® (daunorubicin citrate liposome injection) is an anthracycline used in the treatment of advanced HIV-associated KS.3,5 DaunoXome® is not recommended in patients with less than advanced HIV-related Kaposi’s sarcoma.5
- Galen has recently entered oncology therapeutics by acquiring DaunoXome® from Gilead Sciences, Inc. Galen US, Inc., a wholly owned subsidiary of Galen Ltd., will market DaunoXome® in the United States.

What is HIV-associated Kaposi’s sarcoma (KS)?

- When the body’s immune system is weakened by HIV, infections and cancers like KS can develop.6
- KS is a common malignancy affecting the skin and internal organs.1,2,3

What are the symptoms of KS?

- The most common symptom of KS is the appearance of red or purple patches on the skin. The patches may grow into lumps known as nodules.4,7,8
- KS can also affect the internal organs which can lead to a range of symptoms, depending on which organs are affected.9
- Possible symptoms of KS include:9
  - breathlessness
  - bleeding gums
  - coughing up blood
  - nausea
  - vomiting
  - stomach pain
  - stomach swelling
  - diarrhea
  - leg swelling.

How common is HIV-associated KS?

- KS is the most common HIV-associated malignancy worldwide. The incidence of KS dropped sharply in developed countries in the 1990s, as HIV awareness and prevention efforts grew.10

What is the prognosis for patients with HIV-associated KS?

- The prognosis and treatment options depend on the following:11
  - the type of KS
  - the general health of the patient, especially the immune system
  - the stage of cancer
  - whether the cancer has just been diagnosed or has recurred following treatment.
Who manages HIV patients who develop HIV-associated KS?
- This may vary from country to country, but it does require a multi-disciplinary approach drawing on the skills of HIV specialists, haematologists and cancer specialists (oncologists).³

How are patients with HIV-associated KS treated?
- For the treatment of KS, highly active antiretroviral therapy (HAART) is used to slow the progression of AIDS. If the disease advances or is poorly controlled, chemotherapy treatment may be added into the regimen.³,⁴
- The drug molecules of liposomal anthracyclines are encapsulated in a lipid-based coating known as a liposome. DaunoXome® (daunorubicin citrate liposome injection) is a liposomal anthracycline commonly used in treatment of advanced HIV-associated KS:³
  - as a 40mg/m² intravenous infusion every two weeks.⁵ Treatment should be continued until there is evidence of progressive disease or until other intercurrent complications of HIV disease preclude continuation of therapy.⁵

What are the common side effects of chemotherapy treatment?
- Chemotherapy commonly causes side effects, which usually gradually disappear when treatment is discontinued. Some of the common side effects are:¹²
  - increased risk of infection (neutropenia) - chemotherapy can reduce the number of white blood cells produced by the bone marrow, making patients more prone to infection
  - bruising or bleeding - chemotherapy can also reduce the production of platelets, which help the blood to clot
  - soreness and redness of the palms of the hands and soles of the feet (hand-foot syndrome)
  - anemia - this may make patients feel tired and breathless
  - nausea and vomiting
  - sore mouth and ulcers
  - hair loss (alopecia).

Are there any benefits of liposomal daunorubicin compared with pegylated doxorubicin?
- There are no direct comparative studies between the two types of liposomal anthracyclines. Clinicians must make treatment decisions based on a balance of efficacy, tolerability and cost.

Is DaunoXome® (daunorubicin citrate liposome injection) still available? Was there some historical issue with supply?
- DaunoXome® was previously distributed by Gilead Sciences, Inc. Galen 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. DaunoXome® is available in a number of countries with full medical and marketing support from Galen.

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 enquiry or wish to report a side effect relating to DaunoXome® to the company, call 1-855-DAUNOXOME (1855-328-669663).
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**

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