Time to consider the potent alternative*

*New pre-clinical data raise doubts over claims that bicalutamide is 5-10 times as potent as Drogenil. Recent studies suggest that Drogenil is in fact at least 3 times as potent as bicalutamide.¹

Unlike bicalutamide, Drogenil has proven efficacy at recommended doses in numerous monotherapy and combination studies.²

Even at 150mg daily, bicalutamide monotherapy has been found to be statistically inferior in terms of survival compared to orchiectomy.³

When time is precious, choose the proven alternative.

When time is precious in prostate cancer
DaunoXome is a powerful new anticancer agent. It is the anthracycline, daunorubicin, encapsulated in Nexstar's unique liposomal delivery system. It represents a major advance for cancer chemotherapy-selective targeting of tumours. Protected from metabolism inside small unilamellar vesicles, daunorubicin can be delivered in high concentrations to the interior of the tumour cell, whilst minimising damage to normal tissue.

The first indication for DaunoXome is AIDS-related Kaposis's sarcoma. Clinical response rates in excess of 60% have been reported in phase II studies,1 and in a phase III study, efficacy comparable with combination chemotherapy [ABV]2 has been demonstrated. Serious side-effects typical of anthracyclines, have been mild or even absent with DaunoXome.

Cardiotoxicity, in particular, has not been reported even at cumulative doses <1,000mg/m². Alopecia and neuropathy have been significantly lower than with ABV.2

With the introduction of DaunoXome, the world's first liposomal anti-cancer agent, targeted chemotherapy has become a clinical reality.

DaunoXome SUMMARY OF PRODUCT CHARACTERISTICS Abbreviated version: Trade Name of the Medicinal Product: DaunoXome Injection (liposomal daunorubicin). Pharmaceutical Form: Each 50 ml vial contains 50 mg daunorubicin in a sterile liposomal emulsion. The product is an injectable intended to be administered by intravenous infusion. Clinical Particulars: THERAPEUTIC INDICATIONS: DaunoXome is indicated for the treatment of advanced HIV-related Kaposis's sarcoma. POSSOLOGY AND METHOD OF ADMINISTRATION: Doseage of DaunoXome must be adjusted for each patient. Therapy should be instituted at 40mg/m² every two weeks. Therapy should be continued as long as disease control can be maintained. DaunoXome should be diluted with 5% Dextrose Injection [DSW] before administration. The recommended concentration after dilution is between 0.2 mg and 1 mg daunorubicin/ml of solution. DaunoXome should be administered intravenously over a 30-60 minute period and within six hours of dilution with DSW. Safety and effectiveness in children and the elderly has not been established. CONTRAINDICATIONS: DaunoXome is a bone marrow suppressor. Suppression may occur in patients given therapeutic doses of this drug. Combination of DaunoXome with other cancer chemotherapeutic agents which suppress blood counts is contraindicated. Therapy with DaunoXome is contraindicated in patients who have had a serious hypersensitivity reaction to previous doses of DaunoXome or to any of its constituents unless the benefit from such treatment warrants the risk. INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION: No interactions between DaunoXome and other drugs have been observed to date. Concomitant use of DaunoXome and parenteral nutritional lipid solutions or other liposomal products should be avoided. PREGNANCY AND LACTATION: Safety for use of DaunoXome in pregnant and lactating women has not been established. Since it is not known if the administration of DaunoXome during pregnancy can cause fetal harm, DaunoXome should only be used during pregnancy if the possible benefits to be derived outweigh the potential risks involved. Breast feeding should be discontinued during treatment. EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Since DaunoXome is being administered to sick patients and may induce delayed nausea and vomiting, administration prior to driving or the use of heavy machinery is contraindicated. UNDESIRABLE EFFECTS: Conventional daunorubicin has been associated with cardiomyopathy and congestive heart failure. Although no such side-effects have been observed in the clinical use of DaunoXome, there must be a presumption that this is possible. As such, cardiac function should be evaluated in each patient, including history, physical examination, and appropriate measures of cardiac ejection fraction as indicated. Conventional daunorubicin has also been associated with local tissue necrosis at the site of drug infiltrations. No such local necrosis has been observed with DaunoXome. Nonetheless, care should be taken to ensure that there is no infiltration of drug when DaunoXome is administered intravenously. The primary toxicity of DaunoXome is myelosuppression and, as such, close patient observation and frequent monitoring of the blood cell counts is mandated. Back pain, flushing and chest tightness were occasionally reported during the clinical trials. This combination of symptoms does not always appear to be dose related, and generally occurs during the first ten minutes of the infusion. The symptoms usually subside when the infusion is slowed or halted, and acetaminophen [paracetamol] may be used for analgesia. Other allergic or immune reactions may also be seen, and have been reported to be associated with hypotension. Anaphylactic reactions have been reported in rare cases. Various other minor reactions, such as headache, fatigue, chill, nausea, and vomiting, have also been reported. Legal Category: POM. Marketing Authorization Holder: Nexstar Pharmaceuticals Limited, The Quorum, Barnwell Road, CBS BRE Cambridge. Marketing Authorization Number: PL 11972/0002. Date of First Authorisation / Renewal of Authorization: 11 October 1995. Date of (Part) Revision of the Text: 24/10/95. Price: 50ml vial, £155. Date of Preparation: June 1996. DaunoXome is a trademark. References: 1. Prentice CA. Presented at 2nd Int Congr Drug Ther in HIV infect, Glasgow, November 1994. 2. Gill PS et al (in press).