

ischaemic heart disease · leucopenia · mucositis · myocardial infarction · nail discolouration · nausea · nephropathy · neutropenia · oedema · pain · paraesthesia · pleural effusion · radiation injuries · shock · skin reactions · stomatitis · thrombocytopenia · thrombophlebitis · urine red · venous sclerosis · vomiting

SIDE-EFFECTS, FURTHER INFORMATION Cardiotoxicity is cumulative and may be irreversible, however responds to treatment if detected early.

- **CONCEPTION AND CONTRACEPTION** Contraceptive advice required, see *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
- **PREGNANCY** Avoid (teratogenic and carcinogenic in animal studies). See also *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
- **BREAST FEEDING** Discontinue breast-feeding.
- **HEPATIC IMPAIRMENT** For solution for infusion manufacturer advises caution. For powder for solution for infusion manufacturer advises caution in mild to moderate impairment; avoid in severe impairment.
Dose adjustments Manufacturer advises dose reduction according to serum bilirubin concentration—consult product literature.
- **RENAL IMPAIRMENT** Avoid in severe impairment.
Dose adjustments Reduce dose by 25% if serum creatinine 105–265 micromol/litre.
Reduce dose by 50% if serum creatinine greater than 265 micromol/litre.
- **MONITORING REQUIREMENTS** Cardiac monitoring essential.
- **PRESCRIBING AND DISPENSING INFORMATION** Daunorubicin is available as *conventional* and *liposomal* formulations. These different formulations vary in their licensed indications, pharmacokinetics, dosage and administration, and are **not** interchangeable.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Solution for infusion

- ▶ **DaunoXome** (Galen Ltd)
Daunorubicin (as Daunorubicin hydrochloride citrate liposomal pegylated) 2 mg per 1 ml DaunoXome 50mg/25ml concentrate for solution for infusion vials | 1 vial [PoM] £250.00

Powder for solution for infusion

- ▶ **Daunorubicin (Non-proprietary)**
Daunorubicin (as Daunorubicin hydrochloride) 20 mg Daunorubicin 20mg powder for solution for infusion vials | 10 vial [PoM] £715.00 (Hospital only)

Daunorubicin with cytarabine

24-Jan-2019

The properties listed below are those particular to the combination only. For the properties of the components please consider, daunorubicin p. 950, cytarabine p. 959.

● INDICATIONS AND DOSE

Acute myeloid leukaemia

- ▶ BY INTRAVENOUS INFUSION
- ▶ Adult: (consult product literature)

- **CAUTIONS** Wilson's disease or other copper-related disorders (each vial contains 100 mg of copper gluconate, equivalent to 14 mg of elemental copper)
- **INTERACTIONS** → Appendix 1: anthracyclines · cytarabine
- **HEPATIC IMPAIRMENT** Manufacturer advises caution in severe impairment.
- **RENAL IMPAIRMENT** Manufacturer advises caution in severe impairment.
- **PRESCRIBING AND DISPENSING INFORMATION** Daunorubicin with cytarabine is available as a *liposomal* formulation. This is **not** interchangeable with other

daunorubicin- or cytarabine-containing preparations; such preparations differ in their licensed indications, pharmacokinetics, dosage and administration.

● NATIONAL FUNDING/ACCESS DECISIONS

NICE decisions

- ▶ **Liposomal cytarabine–daunorubicin for untreated acute myeloid leukaemia (December 2018)** NICE TA552
Liposomal cytarabine–daunorubicin (Vyxeos[®]) is recommended, within its marketing authorisation, as an option for untreated therapy-related acute myeloid leukaemia or acute myeloid leukaemia with myelodysplasia-related changes in adults. It is recommended only if the manufacturer provides it according to the commercial arrangement.
www.nice.org.uk/guidance/ta552

Scottish Medicines Consortium (SMC) decisions

SMC No. SMC2130

The *Scottish Medicines Consortium* has advised (March 2019) that liposomal daunorubicin with cytarabine (Vyxeos[®]) is accepted for use within NHS Scotland for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (AML) or AML with myelodysplasia-related changes. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Powder for solution for infusion

- ▶ **Vyxeos** (Jazz Pharmaceuticals UK)
Daunorubicin 44 mg, Cytarabine 100 mg Vyxeos liposomal 44mg/100mg powder for concentrate for solution for infusion vials | 1 vial [PoM] £4,581.00 (Hospital only)

Doxorubicin hydrochloride

21-Nov-2019

● INDICATIONS AND DOSE

Acute leukaemias | Hodgkin's lymphoma | Non-Hodgkin's lymphoma | Some solid tumours including breast cancer | Advanced soft-tissue sarcoma

- ▶ BY INTRAVENOUS INJECTION
- ▶ Adult: (consult product literature)

Some papillary bladder tumours (bladder instillation) | Recurrent superficial bladder tumours (bladder instillation) | Transitional cell carcinoma (bladder instillation) | Carcinoma in situ (bladder instillation)

- ▶ BY INTRAVESICAL INSTILLATION
- ▶ Adult: (consult product literature)

CAELYX[®]

For AIDS-related Kaposi's sarcoma in patients with low CD4 count and extensive mucocutaneous or visceral disease | Advanced ovarian cancer when platinum-based chemotherapy has failed | Progressive multiple myeloma (in combination with bortezomib) in patients who have received at least one prior therapy and who have undergone or are unsuitable for bone-marrow transplantation | Monotherapy for metastatic breast cancer in patients with increased cardiac risk

- ▶ BY INTRAVENOUS INFUSION
- ▶ Adult: (consult product literature)

- **CONTRA-INDICATIONS** Consult product literature
- **CAUTIONS** Cardiac disease · caution in handling—irritant to tissues · consult product literature · elderly · hypertension · previous myocardial irradiation
- **INTERACTIONS** → Appendix 1: anthracyclines
- **SIDE-EFFECTS**
- ▶ **Common or very common** Alopecia · anaemia · anxiety · appetite decreased · arrhythmias · arthralgia · asthenia ·