**ChemoCare Entry for Vyxeos - Liposomal Daunorubicin and Cytarabine**

**Indication**

Vyxeos is indicated for the treatment of adults with high-risk acute myeloid leukaemia (AML) as defined by therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

**Product**

Vyxeos is a combination of the antineoplastic drugs daunorubicin and cytarabine encapsulated in CombiPlex® liposomes for intravenous (IV) administration. Daunorubicin and cytarabine are encapsulated within the CombiPlex® liposomes in a 1:5 molar ratio, a ratio which has been shown to exhibit synergy in promoting leukaemia cell death in both in vitro and in vivo models.

Vyxeos is given according to the following schedule:

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Dosing schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>First induction</td>
<td>daunorubicin 44 mg/m² and cytarabine 100 mg/m² on days 1, 3, and 5</td>
</tr>
<tr>
<td>Second induction</td>
<td>daunorubicin 44 mg/m² and cytarabine 100 mg/m² on days 1 and 3</td>
</tr>
<tr>
<td>Consolidation</td>
<td>daunorubicin 29 mg/m² and cytarabine 65 mg/m² on days 1 and 3</td>
</tr>
</tbody>
</table>

**The Issue**

ChemoCare calculates the individual patients dose using the patient’s Body Surface Area (BSA) and the dose of the product in this case given in mg/m². The issue is that ChemoCare only has one entry field per product and Vyxeos contains two active ingredients.
The Solution

Recognising that every location will have their own individual ways of doing things, below is a solution for the entry of Vyxeos into ChemoCare.

There are two pieces of information that are pivotal to the solution. The dose per m² used to calculate the individual patients dose and the concentration used to calculate the volume to be drawn up from the vial upon reconstitution.

To make this work in ChemoCare the doses and concentrations for the two component parts of Vyxeos are simply added together. So to get the dose for entry into ChemoCare the two doses of Vyxeos are added together thus getting a resultant dose of 144mg/m² (daunorubicin 44 mg/m² and cytarabine 100 mg/m²).

Likewise the two concentrations following reconstitution are also added together giving 7.2mg/ml (2.2 mg/mL daunorubicin and 5 mg/mL cytarabine).

Other important information to capture includes:

- The requirement to give Vyxeos through a line that contains no filter (Including no filter in the drip chamber)
- Infusion time is 90mins
- Infusion fluid is Sodium Chloride 0.9% (500ml)
- Stability once reconstituted is 4hrs
- The dose in consolidation is different from that in inductions 1 and 2

Below are screen shots of all the entry screens as examples. Also attached are examples of the Parenteral Cytotoxic Charts for Induction 1, Induction 2 and consolidation along with the pharmacy worksheet and a copy of the SmPC.
Drug Entry Screens

Drug Formulary - VYXEOS

- Archived: [ ]
- Drug: VYXEOS

- Side Effects:
  - 1 - Low: Myelosuppression, Emesis, Alopecia, Renal
  - 2 - Medium: Neutropenia, Ototoxicity, Diarrhoea, Mucositis
  - 3 - High
  - Very High

- Type: Cytotoxic

- Other Effects:

[Edit] [Delete] [Close]
Regimen and Protocol Entry Screens
### Course Modification

**Course:** VYXEOS IND 1

**Supplemental Text:** VYXEOS Daunorubicin/Cytarabine 44/100mg/m² Ind 1

#### General

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Days</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>D</td>
<td>3</td>
<td>Treatment</td>
</tr>
<tr>
<td>D</td>
<td>5</td>
<td>Treatment</td>
</tr>
<tr>
<td>X</td>
<td>35</td>
<td>Review</td>
</tr>
</tbody>
</table>

#### Cycle Definition

**Version Number:** 1.00

<table>
<thead>
<tr>
<th>Treatment Day</th>
<th>Route</th>
<th>Vehicle</th>
<th>Calc</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>IV Infusion</td>
<td>Sodium Chloride 0.9%</td>
<td>SA</td>
<td>144,000 mg</td>
</tr>
<tr>
<td></td>
<td>VYXEOS Daunorubicin 2.2 mg/ml and C</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

**Print Cycle Definition** **Course Assignment** **Non Trial** **Funded Trial** **Non Funded Trial**

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