

# Systemic Therapy Update



BC Cancer Agency

CARE + RESEARCH

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## For Health Professionals Who Care For Cancer Patients

Available online at: [www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate](http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate)

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### EDITOR'S CHOICE

#### FREQUENTLY ASKED QUESTIONS – ELASTOMERIC INFUSOR<sup>®</sup> RATE

The BCCA Pharmacy Communities Oncology Network (CON) Educators maintain a databank of Oncology-related questions posed by community hospitals. A review of the databank revealed a high frequency of questions related to elastomeric INFUSORS<sup>®</sup> (henceforth referred to as “infusors”) that are used to administer fluorouracil (5-FU). Many questions involve inquiring about why fluorouracil either runs out before or after the expected completion time. Baxter, the manufacturer, was consulted to determine potential causes for rate errors associated with these infusors. The following checklist was developed to guide practitioners in determining the possible causes of deviations from the expected infusion rates for elastomeric infusors. This information will be updated on the BCCA Pharmacy Education website shortly (<http://www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Educators/faqs.htm>).

**Was the deviation from rate within the expected tolerance range?**

Infusors flow within plus or minus 10% of the labelled flow rate. For example, it is generally considered acceptable for 46- or 48-hour infusors to run out within +/- 5 hours of the intended infusion time.

If an infusor runs out too quickly, determine if the patient was given an overdose. A *5-FU infusor overdose* is defined as the administration of 5-FU via infusor at greater than or equal to 2 times the intended rate, with completed delivery of greater than 50% of the intended total 5-FU dose. In the event of an overdose, follow procedures as outlined in the BCCA Management Guideline – Management of 5-FU infusion overdose at the BCCA, Interim

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Guidance, Appendix III.

(<http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Gastrointestinal/5FUOD.htm>)

If an infusor runs out faster than the expected tolerance range, but not fast enough to be considered an overdose, the patient is still at risk for adverse effects. The prescribing physician should be consulted to make a clinical decision about whether any action is required.

**Were there any leaks that may have contributed to an infusor running out early?**

If leaks were present, this could explain why the infusor ran out early.

**Was the wrong infusor selected?**

Compare the infusor code on the BCCA pre-printed order to the one on the infusor (SV2, LV2, LV5 or LV1.5).

SV	Small volume (maximum capacity of 105 mL)
LV	Large volume (maximum capacity of 300 mL)
1.5	1.5 mL/hr fixed flow rate
2	2 mL/hr fixed flow rate
5	5 mL/hr fixed flow rate

If the pre-printed orders list more than one infusor, ensure that the correct infusor was selected for the dose.

Pre-printed orders for protocols containing 46- and 48-hour 5-FU infusions use different sized infusors with different rates depending on the dose:

46-Hour Infusion:

- SV2 for doses less than or equal to 4400 mg
- LV5 for doses greater than 4400 mg

48-Hour Infusion:

- SV2 for doses less than or equal to 4600 mg
- LV5 for doses greater than 4600 mg

**Was normal saline used instead of D5W?**

Normal saline would make the infusor infuse approximately 10% faster than with the intended D5W due to viscosity changes.

**Was the infusor filled with the correct volume?**

Infusors should be filled to at least 80% of their nominal volume or they will infuse faster than the intended rate. The *nominal volume* is the volume at which the infusor has the most accurate flow rate. All BCCA pre-printed orders incorporate at least 80% of the nominal volume. Check the Baxter infusor package insert for nominal volumes if a BCCA pre-printed order is not followed.

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**Was the infusor stored at room temperature?**

Baxter infusors will infuse faster in the heat or slower in the cold due to viscosity changes.

**Was the infusor positioned correctly on the patient (including at night)?**

Elastomeric infusors should be stored close to the same height as the Luer Lock connector. During the day, infusors are generally kept in fanny packs carried around the waist. At night, infusors are kept at bed height. Under the pillow is often recommended. If infusors are placed on the floor below the bed they will run too slowly. If they are placed on a dresser that is higher than the bed, they will run too quickly.

**Was the flow restrictor taped securely to the skin to maintain the correct temperature?**

If the tape comes loose, the flow restrictor temperature may drop, leading to a reduced flow rate.

**Were any sources of obstruction present that could slow or stop flow?**

Examples Include:

- Infection (redness, firmness or swelling at the IV site)
- Kinks or clamps in the tubing
- Air in tubing – Was flow verified by visualizing 2-3 drops of fluid flowing from the restrictor at the time infusor was connected to rule out the presence of air?

**Was the access system (i.e. catheter) used to connect the infusor 22 gauge or larger?**

Anything smaller than 22 gauge may decrease flow.

**BCCA Resources:**

- BCCA Management Guideline - Management of 5-fluorouracil (5FU) infusion overdose at the BCCA, Interim Guidance, Appendix III (<http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/Gastrointestinal/5FUOD.htm>)
- Nursing Practice Reference C-252 – Administration of Chemotherapeutic Agents
- Appendix 7: Patient Teaching Standards – Managing at Home with an Elastomeric Infusion Device (<http://www.bccancer.bc.ca/HPI/Nursing/References/NursingBCCA/C-252.htm>)
- Your Infusor – A Guide for Patients (<http://www.bccancer.bc.ca/HPI/DrugDatabase/DrugIndexPt/INFUSOR™+-+Guide.htm>)
- Supporting Safe Home Discontinuation of INFUSOR™ for BCCA Patients at Home (<http://www.bccancer.bc.ca/HPI/Nursing/whatsnew/default.htm>)
- Safe Disposal of Waste at Home after Chemotherapy (Pt. Info.) (<http://www.bccancer.bc.ca/HPI/DrugDatabase/Appendices/Appendix5/SafeDisposalofWasteatHomeAfterChemotherapyPtInfo.htm>)

**Baxter Resources:**

- Contact Baxter (1-888-719-9955) to log an infusor failure. You will be sent a canister for shipping the infusor to Baxter for testing.
- Baxter Elastomeric Pumps Patient Guide (<http://www.capca.ca/wp-content/uploads/Baxter-Elastomeric-Pumps-Patient-Guide1.pdf>)

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- Baxter Elastomeric Pumps Clinician Guide (<http://www.capca.ca/wp-content/uploads/Baxter-Elastomeric-Pumps-Clinician-Guide11.pdf>)

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## DRUG UPDATE

### SHORTAGE OF PEGYLATED LIPOSOMAL DOXORUBICIN (CAELYX®) – AN UPDATE

Janssen Inc. reported in a written communication last week that the **drug shortage of pegylated liposomal DOXOrubicin (CAELYX®)** will continue to persist. Earlier this month, a quality assurance inspection at Janssen's contract manufacturer, Ben Venue Laboratories (BVL), identified several problems with the facilities' sterilization process. As a result, BVL is suspending all manufacturing and distribution activities until further notice. The current CAELYX® supply will likely be depleted by early December, with no tentative release date for subsequent supplies.

It is recommended that the prescribing of CAELYX® be considered only in patients where there is no viable alternative available. It is also recommended that no new patients be initiated on CAELYX® until further notice. Due to potential compromise in the sterilization process, health professionals should report any associated adverse drug reactions (i.e. fever, sepsis). Reports can be made to:

- Health Canada's MedEffect Canada Vigilance Adverse Reporting Program – via telephone (1-866-234-2345) or online (<https://webprod4.hc-sc.gc.ca/medeffect-medeffet/index-eng.jsp>)
- Janssen Inc's Drug Safety and Surveillance Department at 1-800-567-3331

To review the treatment alternatives for affected chemotherapy protocols, please see the September edition of the System Therapy Update (<http://www.bccancer.bc.ca/HPI/stupdate.htm>). Prescribers and pharmacies will continue to collaborate to allocate the stock for patients already booked for treatment.

## CANCER DRUG MANUAL

### REVISED MONOGRAPHS

**Cladribine Chemotherapy Preparation and Stability Chart** has been updated to include information on SC syringe to the PPC brand.

## CANCER DRUG MANUAL

**Exemestane Monograph** has been revised to update information about grapefruit interactions in the Interaction section. Other monograph changes include: deleting outdated patent information and revision of the Side Effects table and Supply and Storage sections as per the current template standard. The **Patient Handout** has been revised to remove the recommendation to avoid grapefruit and grapefruit juice during treatment.

**Lenalidomide Monograph** has been revised to update the starting dose adjustments for renal impairment in patients with myelodysplastic syndrome and multiple myeloma. Of particular note, dosing recommendations in dialysis patients with multiple myeloma have been changed to 5 mg daily from 15 mg three times weekly following dialysis.

**Procarbazine Monograph** has been revised to update the dosing information in the renal failure and hepatic failure sections.

**RiTUXimab Monograph** has been revised to include new information about concurrent vaccine use in the Caution section.

## LIST OF NEW AND REVISED PROTOCOLS, PRE-PRINTED ORDERS AND PATIENT HANDOUTS

**BC Cancer Agency Protocol Summaries, Provincial Pre-Printed Orders (PPPOs) and Patient Handouts** are revised periodically. New, revised or deleted protocols, PPPOs and patient handouts for this month are listed below. Protocol codes for treatments requiring “Compassionate Access Program” (previously Undesignated Indications Request) approval are prefixed with the letter “U”.

### REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
BRAJACTT	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return Appointment Orders clarified</i>	Adjuvant Therapy for Breast Cancer using DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab
BRAJACTTG	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Return Appointment Orders clarified</i>	Adjuvant Therapy for Breast Cancer using Dose Dense Therapy: DOXOrubicin and Cyclophosphamide followed by PACLitaxel and Trastuzumab
UBRAVLCAP	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Dose modifications for hematology clarified</i>	Therapy for Metastatic Breast Cancer Using Capecitabine and Lapatinib
UCNBEV	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Tests for proteinuria clarified</i>	Palliative Therapy for Recurrent Malignant Gliomas Using Bevacizumab

REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):					
CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
UGICAPIRI	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Extended number of treatment cycles</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Irinotecan and Capecitabine in Patients Unsuitable for G1OLF1RI
UGICAPOX	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Extended number of treatment cycles</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, and Capecitabine
UGIFOLFOX	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Extended number of treatment cycles</i>	Palliative Combination Chemotherapy for Metastatic Colorectal Cancer Using Oxaliplatin, 5-Fluorouracil and Folinic Acid (Leucovorin)
G1PGEM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Revised Eligibility section to allow treatment until progression without CAP approval</i>	Palliative Therapy for Pancreatic Adenocarcinoma, Gallbladder Cancer, and Cholangiocarcinoma Using Gemcitabine
GOOVLDOX	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Diluent for premedications revised</i>	Treatment of Relapsed/ Progressing, Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma Using Pegylated Liposomal DOXOrubicin
HNLALTPRT	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<i>Premedication section updated to allow for optional hydration; chemotherapy administration schedule clarified under Treatment section</i>	Treatment of Locally Advanced (Alternate) Head and Neck Cancer Using C1SPlatin during Radiation Therapy
HNNLAPG	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Clarified blood work for day 1</i>	Induction Treatment of Locally Advanced Nasopharyngeal Cancer with C1SPlatin and Gemcitabine
LYRITB	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<i>Timeframe for dosimetric &amp; therapeutic dose clarified</i>	Summary for Palliative Therapy for Lymphoma Using Radioimmunotherapy: Tositumomab-Priming for I <sup>131</sup> Tositumomab
UMYCTD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Thalidomide access information and contact physician updated</i>	Treatment of Systemic Light-chain (AL) Amyloidosis and Multiple Myeloma Using Cyclophosphamide, Thalidomide and Dexamethasone
UMYBORPRE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests and Dose Modifications sections reformatted for clarity; SC administration sites and contact physician information updated</i>	Treatment of High Risk Multiple Myeloma Using Bortezomib, Dexamethasone with or without Cyclophosphamide as Induction Pre-Stem Cell Transplant
UMYBORREL	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests and Dose Modifications sections reformatted for clarity; SC administration sites and contact physician information updated</i>	Treatment of Relapsed Multiple Myeloma Using Bortezomib, Dexamethasone with or without Cyclophosphamide (Formerly UMYBORTEZ)
UMYMPBOR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Tests and Dose Modifications sections reformatted for clarity; SC administration sites and contact physician information updated</i>	Treatment of Multiple Myeloma using Melphalan, Prednisone and Weekly Bortezomib with the Option of Substituting Cyclophosphamide for Melphalan

**REVISED PROTOCOLS, PPPOs AND PATIENT HANDOUTS (AFFECTED DOCUMENTS ARE CHECKED):**

CODE	Protocol	PPPO	Patient Handout	Changes	Protocol Title
MYPAM	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<i>Minor typo corrected</i>	Treatment of Multiple Myeloma with Pamidronate

## WEBSITE RESOURCES AND CONTACT INFORMATION

WEBSITE RESOURCES	
	<a href="http://www.bccancer.bc.ca">www.bccancer.bc.ca</a>
Reimbursement & Forms: Benefit Drug List, Class II, Compassionate Access Program	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Forms</a>
Cancer Drug Manual	<a href="http://www.bccancer.bc.ca/cdm">www.bccancer.bc.ca/cdm</a>
Cancer Management Guidelines	<a href="http://www.bccancer.bc.ca/CaMgmtGuidelines">www.bccancer.bc.ca/CaMgmtGuidelines</a>
Cancer Chemotherapy Protocols, Pre-printed Orders, Protocol Patient Handouts	<a href="http://www.bccancer.bc.ca/ChemoProtocols">www.bccancer.bc.ca/ChemoProtocols</a>
Systemic Therapy Program Policies	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/Policies</a>
Systemic Therapy Update	<a href="http://www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate">www.bccancer.bc.ca/HPI/ChemotherapyProtocols/stupdate</a>
CON Pharmacy Educators	<a href="http://www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Educators/Pharmacists">www.bccancer.bc.ca/RS/CommunitiesOncologyNetwork/Educators/Pharmacists</a>

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OSCAR	888.355.0355	604.708.2051	oscar@bccancer.bc.ca
Compassionate Access Program (CAP)	604.877.6277	604.708.2026	cap_bcca@bccancer.bc.ca
Pharmacy Chemotherapy Certification	250.712.3900 x 686741		rxchemocert@bccancer.bc.ca
BCCA-Abbotsford Centre	604.851.4710 Toll Free 877.547.3777		
BCCA-Centre for the Southern Interior	250.712.3900 Toll Free 888.563.7773		
BCCA-Fraser Valley Centre	604.930.2098 Toll Free 800.523.2885		
BCCA-Vancouver Centre	604.877.6000 Toll Free 800.663.3333		
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