Bacillus Calmette-Guérin (BCG) (OncoTICE®)

Preparation of a Full Dose of OncoTICE® and Dividing a Full Dose Into Three Equal Doses NOT Using a Closed System Drug Transfer Device

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The typical dose used for intravesical instillation is dictated by brand (***refer to protocol by which patient is being treated***):

OncoTICE® *(Tice* strain) 1 vial = 50 mg = 1 to 8 x 10^8 CFU;

- ***full dose*** **= 50 mg (1 x 50 mg vial)**

The instructions described in these checklists are by no means intended to be regarded as the only acceptable method of preparing or dividing a dose of OncoTICE®.

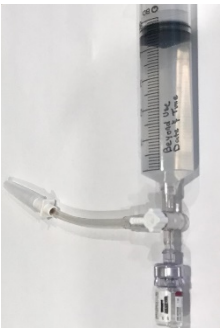
Preparation of a Full Dose (50 mg / 1 Vial) of Bacillus Calmette-Guérin (BCG) (OncoTICE®) Using a MEDXL BCG Medication Administration Kit

Note:

- As long as the syringe and OncoTICE® vial are NOT disconnected from the MEDXL BCG Medication Administration Kit, it is not necessary to use a Closed System Drug Transfer Device to reconstitute one vial of OncoTICE® and dilute in 45 mL of normal saline
- If dividing the full dose of OncoTICE® into three equal (1/3) doses, then use a Closed System Drug Transfer Device is recommended

Supplies:

- ✓ 1 x OncoTICE® 50 mg vial
- ✓ 1 x Intravenous (IV) solution bag of preservative-free normal saline (NS) 0.9%
- ✓ 1 x 50 mL BD syringe
  - Note that a 60 mL syringe may be used in place of the 50 mL BD syringe; the total volume in the syringe after dilution of the drug remains at 45 mL
- ✓ 1 x MEDXL BCG Medication Administration Kit (BCG Kit)



1. withdraw 45 mL of normal saline into the syringe
2. attach the NS-filled syringe to the luer lock end of the BCG Kit; align the 'OFF' arrow with the catheter tip
3. attach the OncoTICE® vial to the other end of the BCG Kit
4. with the vial in an upright position, withdraw approximately 1 mL of air from the vial into the syringe and allow approximately 1 mL of NS to flow back into the vial as pressure in the vial equalizes
5. allow the OncoTICE® suspension to stand for a few minutes, then gently swirl to suspend
6. withdraw the OncoTICE® suspension into the syringe; repeat step 4 as necessary until all drug from the vial has been withdrawn into the syringe
7. align the 'OFF' arrow with the syringe until ready to administer to the patient
8. do not detach the vial or the syringe from the BCG Kit
9. the OncoTICE®-filled syringe MUST be labelled with the **beyond use (expiry) date and time**; the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
10. leftover BCG must **NOT** be saved for a future patient
11. dispose of all supplies used to reconstitute BCG as biohazardous waste according to site-specific policies and procedures

Note:

- **BCG *must* be administered within 2 hours of the start of reconstituting the drug in the vial[1,2]**

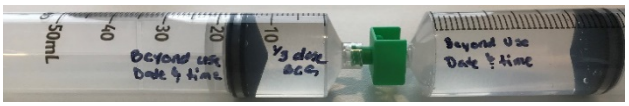
➢ **USE ASEPTIC TECHNIQUE THROUGHOUT**

Dividing a Full Dose (50 mg) of Reconstituted Bacillus Calmette-Guérin (BCG) (OncoTICE®) Into Three Equal (16.7 mg) Doses and Diluting the 16.7 mg Doses with Normal Saline

Supplies:

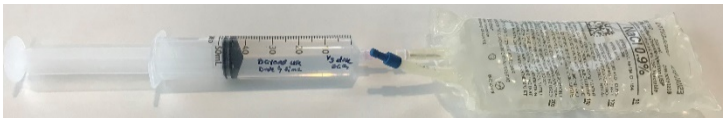
- ✓ 1 x 50 mL BD syringe containing 45 mL (50 mg) of reconstituted OncoTICE® labelled with the **beyond use (expiry) date and time**
  - ➢ ensure the divided doses will be administered to patients before the beyond use (expiry) date and time recorded on the syringe
- ✓ 1 x Intravenous (IV) solution bag of preservative-free normal saline (NS) 0.9%
- ✓ 2 x 50 mL BD syringes
  - Note that a 60 mL syringe may be used in place of the 50 mL BD syringe; the total volume in the syringe after dilution of the drug remains at 45 mL
- ✓ 1 x Syringe Fluid Dispensing Connector
- ✓ 3 x needles
- ✓ 3 x BCG Medication Administration Kits (BCG Kit)

1. luer lock a Syringe Fluid Dispensing Connector to the 50 mL (BD) syringe containing 45 mL (50 mg) of reconstituted OncoTICE®
2. luer lock an **empty 50 mL (BD) syringe** to the other end of the Syringe Fluid Dispensing Connector and record the **beyond use (expiry) date and time** written on the syringe containing 45 mL (50 mg) of OncoTICE® onto the empty 50 mL syringe and that **the contents of the syringe contains a 1/3 dose (16.7 mg) of OncoTICE®**
3. transfer 15 mL (16.7 mg) of OncoTICE® suspension into the empty syringe

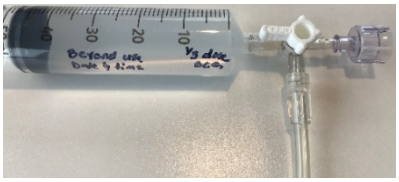


4. disconnect the syringe containing 15 mL (16.7 mg) of OncoTICE® from the Syringe Fluid Dispensing Connector and re-attach the luer lock cap to the Syringe Fluid Dispensing Connector until ready to prepare the next 15 mL (16.7 mg) syringe

5. attach a needle to the syringe containing 15 mL (16.7 mg) and withdraw NS into the syringe until the total volume in the syringe is 45 mL



6. luer lock the syringe containing 45 mL diluted 1/3 dose (16.7 mg) OncoTICE® onto a BCG Kit; align the "OFF" arrow with the syringe until ready to administer to the patient



7. repeat steps 2-6 until all three syringes contain 1/3 OncoTICE® doses (16.7 mg) diluted to 45 mL with NS; the original syringe contains the final 1/3 divided dose of OncoTICE®
8. the prepared doses **MUST** be administered to the patients before the beyond use date and time have passed; leftover BCG must **NOT** be saved for future patients
9. dispose of all supplies used to reconstitute and administer BCG as biohazardous waste according to site-specific policies and procedures

Note:

- **BCG *must* be administered within 2 hours of the start of reconstituting the drug in the vial[1,2]**

➢ **USE ASEPTIC TECHNIQUE THROUGHOUT**

References

1. Merck Canada Inc. OncoTICE® product monograph. Kirkland, Quebec; 29 April 2019
2. The United States Pharmacopeial Convention, Inc. General Chapter 797: Pharmaceutical compounding - sterile preparations Draft. USP 27-NF 22. Rockville, Maryland: The United States Pharmacopeial Convention, Inc.; 2019