

Bacillus Calmette-Guérin (VERITY-BCG®)

Preparation of a Full Dose and a Half Dose of VERITY-BCG® 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*):

VERITY-BCG® (Russian BCG-I strain) 1 vial = 40 mg = 1 to 8 x 10⁸ CFU;

- **full dose = 80 mg (2 x 40 mg vials)**

The instructions described in these checklists are by no means intended to be regarded as the only acceptable method of preparing a full or half dose of VERITY-BCG®.

Preparation of a Full Dose (80 mg / 2 Vials) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit

Note:

- When reconstituting two vials of VERITY-BCG® use of a Closed System Drug Transfer Device is recommended as the system is opened when transferring the drug-filled syringe from the first reconstituted vial to the next.

Supplies:

- ✓ 2 x VERITY-BCG® 40 mg vials
- ✓ 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 needle
- ✓ 1 x chemotherapy vent
- ✓ 1 x MEDXL BCG Medication Administration Kit (BCG Kit)

1. attach a needle to the syringe and withdraw 45 mL of normal saline into the syringe
2. insert the chemotherapy vent into one of the VERITY-BCG® 40 mg vials; ensure the bevel of the chemotherapy vent needle remains high in the vial (close to the vial stopper)
3. insert the needle attached to the NS syringe into the same VERITY-BCG® vial so that the bevel of the needle is positioned lower in the vial than the bevel of the chemotherapy vent needle
4. with the vial in an upright position, inject approximately 1 mL of NS into the vials
5. allow the VERITY-BCG® suspension to stand for a few minutes, then gently swirl to suspend; do not remove either of the needles from the vial
6. withdraw the VERITY-BCG® suspension into the syringe; repeat step 4 as necessary until all drug from the vial has been withdrawn into the syringe
 - ensure the bevel of the chemotherapy vent is not in solution when adding solution to the vial as this will plug the filter on the vent
7. attach the VERITY-BCG® syringe to the luer lock end of the BCG Kit; align the 'OFF' arrow with the catheter tip
8. attach the second VERITY-BCG® 40 mg vial to the other end of the BCG Kit
9. 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 reconstituted VERITY-BCG® to flow back into the vial as pressure in the vial equalizes
10. allow the BCG suspension to stand for a few minutes, then gently swirl to suspend
11. withdraw the BCG suspension into the syringe; repeat step 9 as necessary until all drug from the second vial has been withdrawn into the syringe
12. align the 'OFF' arrow with the syringe until ready to administer to the patient
13. do **not** detach the vial or the syringe from the BCG Kit
14. the VERITY-BCG®-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
15. leftover BCG must **NOT** be saved for a future patient
16. 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**

Preparation of a Half Dose (40 mg / 1 Vial) of Bacillus Calmette-Guérin (VERITY-BCG®) Using a MEDXL BCG Medication Administration Kit

Note:

- As long as the syringe and VERITY-BCG® 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 VERITY-BCG® and dilute in 45 mL of normal saline

Supplies:

- ✓ 1 x VERITY-BCG® 40 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)

- withdraw 45 mL of normal saline into the syringe
- attach the NS-filled syringe to the luer lock end of the BCG Kit; align the 'OFF' arrow with the catheter tip
- attach the VERITY-BCG® vial to the other end of the BCG Kit and record the **beyond use (expiry) date and time** on the syringe and that **the contents of the syringe contains a 1/2 dose (40 mg) of VERITY-BCG®**
- 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
- allow the VERITY-BCG® suspension to stand for a few minutes, then gently swirl to suspend
- withdraw the VERITY-BCG® suspension into the syringe; repeat step 4 as necessary until all drug from the vial has been withdrawn into the syringe
- align the 'OFF' arrow with the syringe until ready to administer to the patient
- do not detach the vial or the syringe from the BCG Kit
- the prepared dose **MUST** be administered to the patient before the beyond use date and time have passed
- leftover BCG must **NOT** be saved for a future patient
- 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**

References

1. Verity Pharmaceuticals Inc. VERITY-BCG® Product Monograph. Mississauga, Ontario; 5 January 2021
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