

Carfilzomib BOS Nurse Checklist

Important for the safe use of Carfilzomib BOS

Carfilzomib BOS (Carfilzomib)
Lyophilized powder for solution for injection

Carfilzomib BOS Brief Prescribing Information

Please refer to the Summary of Product Characteristics before prescribing Carfilzomib BOS

Therapeutic Indications: Carfilzomib BOS is indicated as a single agent for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy in combination with:

- Lenalidomide and dexamethasone; or
- Dexamethasone; or
- Daratumumab and dexamethasone; or
- Daratumumab and hyaluronidase-fihj and dexamethasone

Posology and Method of Administration:

Posology

Carfilzomib BOS is administered intravenously once weekly 20/70 mg/m² (30-minute infusion) in combination with:

- dexamethasone (Kd),
- daratumumab plus dexamethasone (DKd), or
- daratumumab and hyaluronidase-fihj plus dexamethasone (DKd)

The recommended starting dosage of Carfilzomib BOS is 20 mg/m² on Cycle 1, Day 1. If tolerated, escalate the dose to 70 mg/m² on Cycle 1, Day 8. Administer Carfilzomib BOS intravenously as a 30-minute infusion on Days 1, 8, and 15 of each 28-day cycle.

Carfilzomib BOS twice weekly 20/56 mg/m² administered as monotherapy or in combination with:

- dexamethasone (Kd),
- daratumumab plus dexamethasone (DKd), or
- daratumumab and hyaluronidase-fihj plus dexamethasone (DKd)

The recommended starting dosage of Carfilzomib BOS is 20 mg/m² on Cycle 1, Days 1 and 2. If tolerated, escalate the dose to 56 mg/m² on Cycle 1, Day 8. Administer Carfilzomib BOS intravenously as a 30-minute infusion on Days 1, 2, 8, 9, 15, and 16 of each 28-day cycle.

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Patient Name

Date

This checklist is intended for nurses to use prior to dosing each patient and at any follow-up visits or calls with the patient to identify some of the signs and symptoms, associated with adverse reactions related to, treatment with Carfilzomib BOS. Early identification of adverse reactions and interventions are an important part of the safe use of Carfilzomib BOS.

Please note: This checklist is not meant to be all-inclusive

If the patient responds "Yes" to any of these questions, consult the patient's Hematologist before administering Carfilzomib BOS

- | | | |
|--|------------------------------|-----------------------------|
| Do you have swelling of the feet or legs? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you felt drowsy or extremely tired? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you felt dizzy or fainted? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you experienced shortness of breath? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Do you bleed or bruise more easily than normal? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Do you have a fever? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you experienced severe weakness? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you experienced confusion or seizures? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you experienced a loss of sight? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Have you started taking any new medications (prescription, nonprescription, or herbal)? If yes, which and how often? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Do you have chills or shivering? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Are you having chest pain? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Did you have recent myocardial infarction (within the prior 4 months)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Do you have a high heart rate? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Do you have pre-existing hypertension? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Do you have pre-existing cardiac failure (NYHA III or IV)? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Are you experiencing sudden weight change? | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Do you have a cough?

Yes No

Are you severely nauseous and/or vomiting?

Yes No

Have you seen blood or mucus in your stools?

Yes No

Are you currently pregnant or breastfeeding?

Yes No

Notes:

Please see
additional
Important Safety
Information on
the reverse side

Please report adverse events through the following channels:

Boston Oncology Arabia Limited

King Abdelaziz Street, 11562, Riyadh, Saudi Arabia

Phone: 011 245 5311 | Mobile: +966 547 643 672

E-mail: pv@bostononcology.com

The National Pharmacovigilance Centre (NPC)

SFDA Call Centre: 19999 | E-mail: npc.drug@sfd.gov.sa

Website: <https://ade.sfd.gov.sa/>

By reporting side effects, you can help provide more information on the safety of this medicine.

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Important for the safe use of Carfilzomib BOS

What are the possible side effects of Carfilzomib BOS for Injection?

Serious Side Effects

Heart Problems: Carfilzomib BOS can cause heart problems or worsen pre-existing heart conditions. Death due to cardiac arrest has occurred within a day of Carfilzomib BOS administration. You will be closely monitored during treatment.

Kidney Problems: There have been reports of sudden kidney failure in patients receiving Carfilzomib BOS. Your kidney function will be closely monitored during treatment.

Tumor Lysis Syndrome (TLS): Cases of TLS have been reported in patients receiving Carfilzomib BOS, including fatalities. You will be closely monitored during treatment for any signs of TLS. Interrupt Carfilzomib BOS until TLS is managed.

Lung Damage: Cases of lung damage have been reported in patients receiving Carfilzomib BOS, including fatal cases.

Pulmonary Hypertension (high blood pressure in the lungs): There have been reports of pulmonary hypertension in patients receiving Carfilzomib BOS.

Lung Complications: Shortness of breath was reported in patients receiving Carfilzomib BOS. Your lung function will be closely monitored during treatment.

High Blood Pressure: Cases of high blood pressure, including fatal cases, have been reported in patients receiving Carfilzomib BOS. Your blood pressure will be closely monitored during treatment.

Blood Clots: There have been reports of blood clots in patients receiving Carfilzomib BOS. If you are at high risk for blood clots, your doctor can recommend ways to lower the risk.

Infusion Reactions: Symptoms of infusion reactions included fever, chills, joint pain, muscle pain, facial flushing and/or swelling, vomiting, weakness, shortness of breath, low blood pressure, fainting, chest tightness, and chest pain. These symptoms can occur immediately following infusion or up to 24 hours after administration of Carfilzomib BOS.

Very Low Platelet Count: Low platelet levels can cause unusual bruising and bleeding. You will have regular blood tests to check your platelet count during treatment.

Liver Problems: Cases of liver failure, including fatal cases, have been reported in patients receiving Carfilzomib BOS. Your liver function will be closely monitored during treatment.

Blood Problems: Cases of a blood disease called thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/ HUS), including fatal cases, have been reported in patients who received Carfilzomib BOS. Your doctor can monitor your signs and symptoms.

Brain Problems: A nerve disease called Posterior Reversible Encephalopathy Syndrome (PRES), formerly called Reversible Posterior Leukoencephalopathy Syndrome (RPLS), has been reported in patients receiving Carfilzomib BOS. It can cause seizure, headache, lack of energy, confusion, blindness, altered consciousness, and other visual and nerve disturbances, along with high blood pressure. Your doctor can monitor your signs and symptoms.

Fetal Harm: Carfilzomib BOS can cause harm to a fetus (unborn baby) when administered to a pregnant woman. Women should avoid becoming pregnant during treatment with Carfilzomib BOS.

Reference: Carfilzomib BOS Summary of Product Characteristics September 2023