COSELA®

trilaciclib for injection 300 mg

DOSING AND ADMINISTRATION GUIDE FOR COSELA

This brochure includes helpful information about how to prepare, administer, dose, and store COSELA, as well as a link to a comprehensive video with step-by-step instructions for infusing COSELA

INDICATION

COSELA is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

Please see additional Important Safety Information on the last pages of this brochure and accompanying Full Prescribing Information.

HOW TO DOSE COSELA

Dose COSELA prior to every chemotherapy infusion[1]

DOSING FOR A CARBOPLATIN/ETOPOSIDE-CONTAINING REGIMEN (WITH OR WITHOUT IMMUNE CHECKPOINT INHIBITOR)[1]

DAY 1 COSELA prior to carboplatin and etoposide → **DAY 2** COSELA prior to etoposide → **DAY 3** COSELA prior to etoposide → **21-DAY CYCLE**

DOSING FOR TOPOTECAN-CONTAINING REGIMEN

DAY 1 COSELA prior to topotecan → **DAY 2** COSELA prior to topotecan → **DAY 3** COSELA prior to topotecan → **DAY 4** COSELA prior to topotecan → **DAY 5** COSELA prior to topotecan → **21-DAY CYCLE**

The interval between doses of COSELA on sequential days should not be greater than 28 hours.[1]

Monitor for signs and symptoms of injection-site reactions, including phlebitis and thrombophlebitis, during infusion. For severe or life-threatening reactions, stop infusion and permanently discontinue COSELA.

Recommended dose of COSELA:

- COSELA is recommended at 240 mg/m^2 per dose. Administer as a 30-minute intravenous infusion completed within 4 hours before starting chemotherapy on each day chemotherapy is administered[1]
  - **Dosage forms and strengths:** For injection: contains the equivalent of 300 mg of COSELA as a sterile, preservative-free, yellow lyophilized cake in a single-dose vial for reconstitution and further dilution

HOW TO PREPARE COSELA

COSELA® trilaciclib for injection 300 mg

COSELA must be reconstituted and then diluted further prior to IV infusion[1]

- Aseptic technique must be used for reconstitution and dilution
- As with all parenteral drug products, visually inspect COSELA for particulate matter and discoloration prior to administration

Reconstituting COSELA:

Calculate the COSELA dose based on the patient's body surface area (BSA), the total volume of reconstituted COSELA solution required, and the number of COSELA vials needed

Reconstitute each 300 mg vial with 19.5 mL of 0.9% Sodium Chloride Injection or 5% Dextrose Injection, USP using a sterile syringe to obtain a concentration of 15 mg/mL of COSELA

Gently swirl the vial for up to 3 minutes until the sterile lyophilized cake is completely dissolved. Do not shake

Inspect the reconstituted solution for discoloration and particulate matter. Reconstituted COSELA solution should be a clear, yellow solution. Do not use if the reconstituted solution is discolored, cloudy, or contains visible particulates

If needed, the unused reconstituted solution in the vial can be stored at 20°C to 25°C (68°F to 77°F) for up to 4 hours prior to transfer to the infusion bag. Do not refrigerate or freeze

Discard any unused portion after use

Diluting reconstituted COSELA solution:

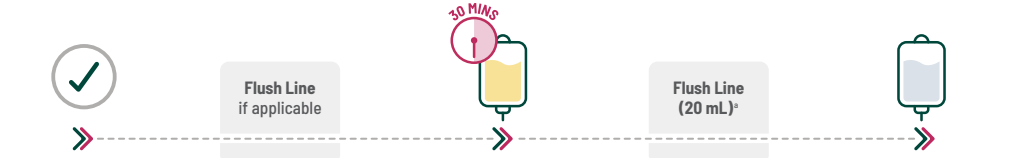
Withdraw the required volume from the vial(s) of reconstituted COSELA solution and dilute into an intravenous infusion bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. The final concentration of the diluted COSELA solution should be between 0.5 mg/mL and 3 mg/mL

Mix diluted solution by gentle inversion. Do not shake

The diluted COSELA solution for infusion is a **clear, yellow solution**

HOW TO ADMINISTER COSELA

Sequence of steps[1]



The interval between doses of COSELA on sequential days ***should not be greater than 28 hours***

[a]Upon completion of infusion of diluted COSELA solution, the infusion line/cannula MUST be flushed with at least 20 mL sterile 5% Dextrose Injection, USP or 0.9% Sodium Chloride Injection, USP.
[b]COSELA can be given within 4 hours before chemotherapy.

- Diluted COSELA solution **MUST** be administered with an infusion set, including an in-line filter (0.2 or 0.22 micron). Compatible in-line filters include polyethersulfone (PES), polyvinylidene fluoride (PVDF), and cellulose acetate (CA)

- **DO NOT** administer diluted COSELA solution with a polytetrafluorethylene (PTFE) in-line filter. PTFE in-line filters are not compatible with diluted COSELA solution
- **DO NOT** co-administer other drugs through the same infusion line
- **DO NOT** co-administer other drugs through a central access device unless the device supports co-administration of incompatible drugs

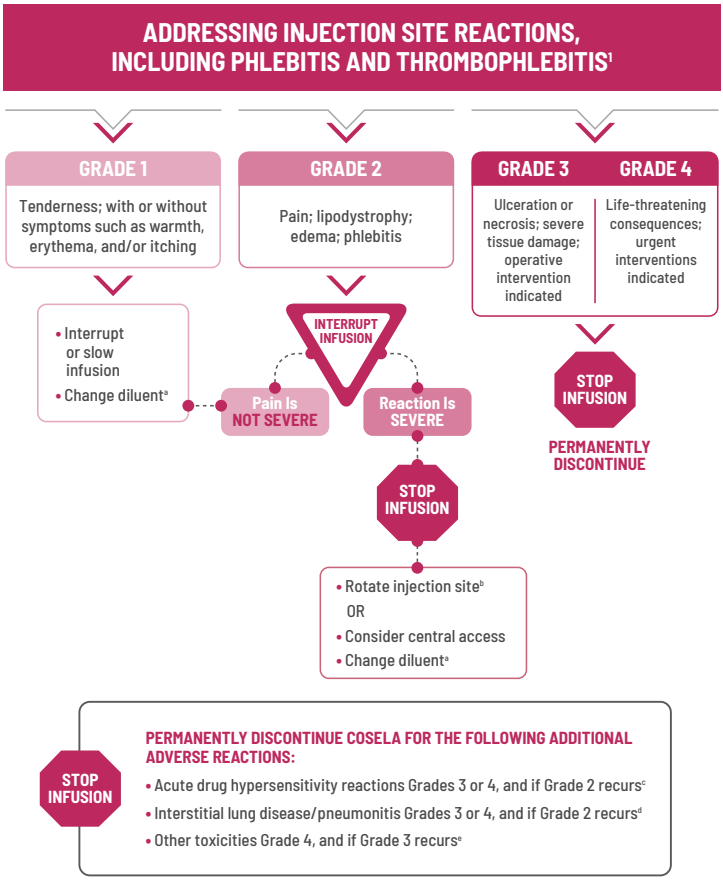
Unexpected therapy interruption

Missed treatment session(s)[1]

If the COSELA dose is missed, discontinue chemotherapy on the day COSELA dose was missed. Consider resuming both COSELA and chemotherapy on the next scheduled day for chemotherapy

Discontinuation of treatment[1]

If COSELA is discontinued, wait 96 hours from the last dose of COSELA before resumption of chemotherapy only



Refer to the Prescribing Information for additional details.
Additional considerations: Ice/cold packs or warm compresses, depending on the patient's symptoms, may be considered per institutional guidelines.[2]

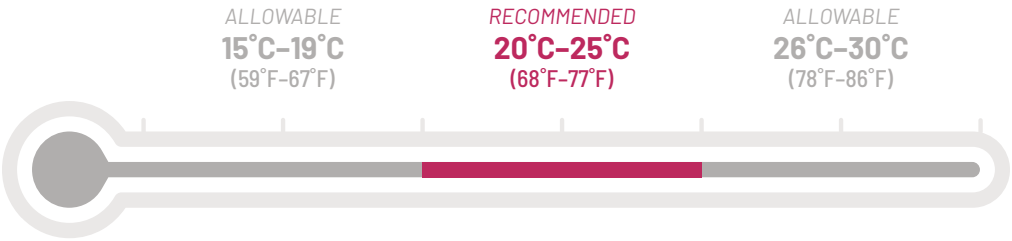
- If 0.9% Sodium Chloride Injection, USP is being used as a diluent/flush, consider changing to 5% Dextrose Injection, USP as appropriate for subsequent infusions[1]
- Note that COSELA is not a vesicant

[a]Please see full Prescribing Information for additional diluent instructions.
[b]Stop infusion in extremity and rotate site of infusion to site in alternative extremity.
[c]Defined as: Grade 2=Moderate; minimal, local, or noninvasive intervention indicated; limited Activities of Daily Living. Grade 3=Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care ADL. Grade 4=Life-threatening respiratory compromise; urgent intervention indicated (eg, tracheotomy or intubation).
[d]Defined as: Grade 2=Symptomatic. Grade 3=Severe symptoms; limiting self-care Activities of Daily Living; oxygen indicated. Grade 4=Life-threatening respiratory compromise; urgent intervention indicated (eg, tracheotomy or intubation).
[e]Grade 3=Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living. Grade 4=Life-threatening respiratory compromise; urgent intervention indicated.

HOW TO STORE COSELA

Store COSELA vials at **20°C to 25°C (68°F to 77°F)**; short-term temperature variations are permitted from **15°C to 30°C (59°F to 86°F)**.[1]

The vial stopper is not made with natural rubber latex.



IV bag materials, diluents, and storage durations at room temperature[1]

IV infusion bag material	Diluent	Diluted COSELA storage duration
Polyvinyl chloride (PVC), Ethylene vinyl acetate (EVA), Polyolefin (PO), or Polyolefin/ Polyamide (PO/PA)	5% Dextrose for Injection, USP	Up to 12 hours at 20°C to 25°C (68°F to 77°F)
PVC, EVA, or PO	0.9% Sodium Chloride Injection, USP	Up to 8 hours at 20°C to 25°C (68°F to 77°F)
PO/PA	0.9% Sodium Chloride Injection, USP	Up to 4 hours at 20°C to 25°C (68°F to 77°F)

To ensure COSELA stability, do not exceed specified storage durations.
If not used immediately, store the diluted COSELA solution in the IV bag as specified here.
Discard if the storage time exceeds these limits. Do not refrigerate or freeze.

IMPORTANT SAFETY INFORMATION, CONTINUED

WARNINGS AND PRECAUTIONS

Injection-Site Reactions, Including Phlebitis And Thrombophlebitis

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

Acute Drug Hypersensitivity Reactions

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

Interstitial Lung Disease/Pneumonitis

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

Embryo-Fetal Toxicity

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

ADVERSE REACTIONS

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.
- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).

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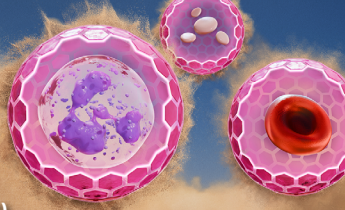

To decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen

For extensive-stage small cell lung cancer (ES-SCLC)

PROTECT THEM ALL

COSELA is the first and only proactive therapy that helps prevent chemotherapy-induced myelosuppression by protecting hematopoietic stem and progenitor cells[1,3]

In the clinical trials, only neutrophils, erythrocytes, and platelets were studied. Hematopoietic stem and progenitor cells, however, are the source of all blood lineages. Additional data is needed to evaluate efficacy beyond what is included in the presented studies.

To see a video on how to infuse COSELA, scan the QR code

If you have additional questions or would like to learn more about COSELA visit **www.COSELAhcp.com**

IMPORTANT SAFETY INFORMATION, CONTINUED

ADVERSE REACTIONS, CONTINUED

- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

DRUG INTERACTIONS

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

To report suspected adverse reactions, contact Pharmacosmos Therapeutics at 1-800-790-4189 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This information is not comprehensive. Please see accompanying Full Prescribing Information.

References: 1. COSELA (trilaciclib) Prescribing Information. Pharmacosmos Therapeutics; 2025. **2.** Gorski L, Hadaway L, Hagle M, et al. Infusion therapy standards of practice. *J Infus Nurs*. 2006;29:S1-S92. **3.** Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib prior to chemotherapy and atezolizumab in patients with newly diagnosed extensive-stage small cell lung cancer: a multicentre, randomised, double-blind, placebo-controlled phase II trial. *Int J Cancer*. 2021;148:2557-2570.

PHARMACOSMOS THERAPEUTICS