90 mm

225 mm

Lurbin™

Lurbinectedin INN for Injection

DESCRIPTION

Lurbin™ is a preparation of Lurbinectedin. It is an alkylating drug that binds guanine residues in the minor groove of DNA, forming adducts and resulting in a bending of the DNA helix towards the major groove. Adduct formation triggers a cascade of events that can affect the subsequent activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in perturbation of the cell cycle and eventual cell death. Lurbinectedin inhibited human monocyte activity in vitro and reduced macrophage infiltration.

INDICATIONS

Lurbinectedin is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.

DOSAGE AND ADMINISTRATION

Recommended Dosage

The recommended dosage of Lurbinectedin is 3.2 mg/m^2 by intravenous infusion over 60 minutes every 21 days until disease progression or unacceptable toxicity.

Initiate treatment with Lurbinectedin only if absolute neutrophil count (ANC) is at least 1,500 cells/mm^3 and platelet count is at least 100,000/mm^3.

Dosage Modifications for Adverse Reactions

Dose Reduction	Total Dose
First	2.6 mg/m^2 every 21 days
Second	2 mg/m^2 every 21 days

Permanently discontinue Lurbinectedin in patients who are unable to tolerate a dose of 2 mg/m^2 or need a dose delay of more than two weeks.

Preparation & Administration

- Inject 8 mL of Sterile Water for Injection USP into the vial, yielding a solution containing 0.5 mg/mL Lurbinectedin. Shake the vial until complete dissolution.
- Visually inspect the solution for particulate matter and discoloration. The reconstituted solution is a clear, colorless or slightly yellowish solution, essentially free of visible particles.
- Calculate the required volume of reconstituted solution as follows:

$$\text{Volume (mL)} = \frac{\text{Body Surface Area (m}^2\text{) x Individual Dose (mg/m}^2\text{)}}{\text{0.5 mg/mL}}$$

- For administration through a central venous line, withdraw the appropriate amount of reconstituted solution from the vial and add to an infusion container containing at least 100 mL of diluent (0.9% Sodium Chloride Injection or 5% Dextrose Injection).
- For administration through a peripheral venous line, withdraw the appropriate amount of reconstituted solution from the vial and add to an infusion container containing at least 250 mL of diluent (0.9% Sodium Chloride Injection or 5% Dextrose Injection).
- Do not co-administer Lurbinectedin and other intravenous drugs concurrently within the same intravenous line.

CONTRAINDICATIONS

Patients with a history of hypersensitivity to the active substance.

SIDE EFFECTS

The most common adverse reactions, including laboratory abnormalities, (≥ 20%) are leukopenia, lymphopenia, fatigue, anemia, neutropenia, increased creatinine, increased alanine aminotransferase, increased glucose, thrombocytopenia, nausea, decreased appetite, musculoskeletal pain, decreased albumin, constipation, dyspnea, decreased sodium, increased aspartate aminotransferase, vomiting, cough, decreased magnesium and diarrhea.

PRECAUTIONS AND WARNINGS

- Myelosuppression: Monitor blood counts prior to each administration. Initiate treatment with Lurbinectedin only if baseline neutrophil count is ≥ 1,500 cells/mm^3 and platelet count is ≥ 100,000/mm^3. Withhold, reduce the dose, or permanently discontinue Lurbinectedin.
- Hepatotoxicity: Monitor liver function tests prior to initiating Lurbinectedin, periodically during treatment and as clinically indicated. Withhold, reduce the dose, or permanently discontinue Lurbinectedin based on severity.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females and males of reproductive potential of the potential risk to a fetus and to use an effective method of contraception.

USE IN PREGNANCY AND LACTATION

Lurbinectedin can cause fetal harm when administered to a pregnant woman. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes.
There is no data on Lurbinectedin in human milk or its effects on breastfed children or milk production. Due to potential serious adverse reactions, advise women not to breastfeed during treatment with Lurbinectedin and for 2 weeks after the last dose.

PEDIATRIC USE

The safety and effectiveness of Lurbinectedin in pediatric patients have not been established.

DRUG INTERACTION

- Strong or moderate CYP3A inhibitors: Coadministration of Lurbinectedin with a strong or a moderate CYP3A inhibitor like Itraconazole may increase Lurbinectedin systemic exposure which may increase the incidence and severity of adverse reactions to Lurbinectedin.
- Strong or moderate CYP3A inducers: Coadministration of Lurbinectedin with a strong CYP3A inducer like Bosentan may decrease Lurbinectedin systemic exposure, which may decrease the efficacy of Lurbinectedin.

PHARMACEUTICAL PRECAUTION

Store in a refrigerator (2 °C to 8 °C temperature) in the original carton until time of reconstitution. If not used immediately after reconstitution or dilution, the **Lurbin**™ solution can be stored prior to administration for up to 24 hours following reconstitution, including infusion time, at either room temperature/ ambient light or in a refrigerator at 2 °C - 8 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Lurbin™ for injection: Each box contains

- One vial of Lurbinectedin INN 4 mg
- One 10 mL ampoule of sterile Water for Injection USP
- One 10 mL disposable syringe
- One infusion set
- One alcohol pad

SK+F ONCOLOGY
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM2195 V01

PM SPECIFICATION

Creative ID: CSD_02

Job Name: Lurbin Injection Insert		**Size:** L - 225 mm, W - 90 mm		**Paper:** 70 gsm Offset Paper
No. of Color: 2 Extra	**Pantone Color Code**	2347	Black C	

	Creative Service Department	Marketing Department	PD/QC/Contract Customer	Approved By
Comments				
Signature & Date				