HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use HERNEXEOS safely and effectively. See full prescribing information for HERNEXEOS.

HERNEXEOS® (zongertinib tablets), for oral use
Initial U.S. Approval: 2025

---------- RECENT MAJOR CHANGES----------

Indications and Usage (1)	2/2026
Dosage and Administration (2.1)	7/2026

----------INDICATIONS AND USAGE----------

HERNEXEOS is a kinase inhibitor indicated for the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-authorized test. (1)

This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. (1)

----------DOSAGE AND ADMINISTRATION----------

- Select patients for treatment with HERNEXEOS based on the presence of HER2 (ERBB2) tyrosine kinase domain activating mutations. (2.1)
- The recommended dosage of HERNEXEOS is based on body weight: (2.2)
  - Patients weighing less than 90 kg: 120 mg (2.2)
  - Patients weighing 90 kg or greater: 180 mg (2.2)
- Take HERNEXEOS orally once daily with or without food until disease progression or unacceptable toxicity. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets: 60 mg (3)

----------CONTRAINDICATIONS----------

None. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hepatotoxicity: Monitor liver function tests including ALT, AST, and total bilirubin at baseline prior to administration, every 2 weeks during the first 12 weeks, and then monthly thereafter as clinically indicated, with more frequent testing in patients who develop transaminase elevations. Interrupt, reduce the dose, or permanently discontinue HERNEXEOS based on severity. (5.1)
- Left Ventricular Dysfunction: Monitor LVEF at baseline prior to administration and at regular intervals during treatment and as clinically indicated. Interrupt, reduce the dose, or permanently discontinue HERNEXEOS based on severity. (5.2)
- Interstitial Lung Disease/Pneumonitis: Monitor for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Interrupt, reduce the dose, or permanently discontinue HERNEXEOS based on severity. (5.3)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. (5.4)

----------ADVERSE REACTIONS----------

- Most common adverse reactions (≥ 20%) are diarrhea, rash, hepatotoxicity, fatigue, nausea, musculoskeletal pain, and upper respiratory tract infection. (6.1)
- The most common (≥ 2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes, increased alanine aminotransferase, increased aspartate aminotransferase, increased gamma glutamyl transferase, decreased potassium, and decreased neutrophils. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

- Strong CYP3A Inducers: Avoid concomitant use with strong CYP3A inducers. If concomitant use cannot be avoided, increase HERNEXEOS dose. (7.1)
- BCRP Substrates: Avoid concomitant use with certain BCRP substrates where minimal concentration increase may lead to serious adverse reactions and consider alternative therapies. If concomitant use cannot be avoided, monitor patients closely for adverse reactions and follow recommendations provided in the BCRP substrate approved product labeling. For other BCRP substrates, monitor for increased adverse reactions and adjust the dosages of those substrates as clinically appropriate. (7.2)

----------USE IN SPECIFIC POPULATIONS----------

- Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 7/2026

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

HERNEXEOS is indicated for the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-authorized test *[see Dosage and Administration (2.1)]*.

This indication is approved under accelerated approval based on objective response rate and duration of response *[see Clinical Studies (14)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 DOSAGE AND ADMINISTRATION

2.1 Patient Selection

Select patients for treatment of unresectable or metastatic NSCLC based on the presence of HER2 (ERBB2) tyrosine kinase domain activating mutations in tumor or plasma specimens *[see Clinical Studies (14)]*. If no mutation is detected in a plasma specimen, test tumor tissue. Information on FDA-authorized tests for HER2 (ERBB2) tyrosine kinase domain activating mutations is available at: http://www.fda.gov/CompanionDiagnostics.

2.2 Recommended Dosage and Administration

The recommended dosage of HERNEXEOS is based on body weight:

- Patients weighing less than 90 kg: 120 mg
- Patients weighing 90 kg or greater: 180 mg

Take HERNEXEOS orally once daily with or without food until disease progression or unacceptable toxicity. Swallow HERNEXEOS tablets whole with water. Do not split, crush, or chew tablets.

Missed Dose

If a dose is missed within 12 hours, take the dose. If a dose is missed by more than 12 hours, skip the missed dose and take the next scheduled dose.

Vomited Dose

If a dose is vomited, do not take an additional dose. Take the next dose at the regularly scheduled time.

2.3 Dosage Modifications for Adverse Reactions

The recommended dose reductions for adverse reactions are presented in Table 1.

Table 1 Recommended HERNEXEOS Dose Reductions for Adverse Reactions

Current HERNEXEOS Dose	First Reduction	Second Reduction
180 mg	120 mg	60 mg
120 mg	60 mg	Permanently discontinue
Permanently discontinue HERNEXEOS in patients who are unable to tolerate 60 mg once daily.		

The recommended dosage modifications for adverse reactions are presented in Table 2.

Table 2 Recommended HERNEXEOS Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification

Hepatotoxicity *[see Warnings and Precautions (5.1)]*	Grade 3 or 4 ALT and/or AST *without* increased total bilirubin	• Interrupt HERNEXEOS until recovered to ≤ Grade 1 or baseline. • Resume HERNEXEOS at reduced dose level.
	Grade 3 total bilirubin	• Interrupt HERNEXEOS until recovered to ≤ Grade 1 or baseline. • Resume HERNEXEOS at reduced dose level.
	Grade 4 total bilirubin	• Permanently discontinue HERNEXEOS.
	ALT or AST ≥ 3x ULN *with* total bilirubin ≥ 2x ULN	• Permanently discontinue HERNEXEOS.
Left Ventricular Dysfunction *[see Warnings and Precautions (5.2)]*	LVEF 40 to 50% and decrease from baseline of 10 to 19%	• Interrupt HERNEXEOS until recovered to ≤ Grade 1 or within 10% from baseline. • If recovered to ≤ Grade 1 in ≤ 4 weeks, resume HERNEXEOS at the same dose level. • If not recovered to ≤ Grade 1 within 4 weeks, permanently discontinue HERNEXEOS.
	LVEF 20 to 39% or ≥ 20% decrease from baseline	• Interrupt HERNEXEOS until recovered to ≤ Grade 1 or within 10% from baseline. • If recovered to ≤ Grade 1 in ≤ 4 weeks, resume HERNEXEOS at the reduced dose level. • If not recovered to ≤ Grade 1 within 4 weeks, permanently discontinue HERNEXEOS.
	Symptomatic Congestive Heart Failure	• Permanently discontinue HERNEXEOS.
Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.3)]*	Grade 2	• Withhold HERNEXEOS until resolution. • Resume HERNEXEOS at reduced dose level. • Permanently discontinue HERNEXEOS for recurrent ILD/pneumonitis.
	Grade 3 or Grade 4	• Permanently discontinue HERNEXEOS.
Diarrhea *[see Adverse Reactions (6.1)]*	Grade 2	• Maintain HERNEXEOS dose. • Initiate anti-diarrheal treatment.
	Grade 2 lasting ≥ 2 days despite anti-diarrheal treatment	• Interrupt HERNEXEOS until recovered to ≤ Grade 1. • Resume HERNEXEOS at reduced dose level.
	Grade 3 or Grade 4	• Interrupt HERNEXEOS until recovered to ≤ Grade 1. • Resume HERNEXEOS at reduced dose level. • Permanently discontinue HERNEXEOS if diarrhea does not resolve to ≤ Grade 1 within 14 days, despite optimal supportive care (including anti-diarrheal treatment) and treatment interruption.
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Grade 3	• Interrupt HERNEXEOS until recovered to ≤ Grade 1 or baseline.

		• Resume HERNEXEOS at reduced dose level.
	Grade 4	• Permanently discontinue HERNEXEOS.

ALT = alanine aminotransferase; AST = aspartate aminotransferase; ULN = upper limit of normal
*Based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0

2.4 Dosage Modifications for Drug Interactions

Strong CYP3A Inducers

Avoid concomitant use of strong CYP3A inducers with HERNEXEOS.
If concomitant use cannot be avoided, increase the HERNEXEOS dose based on body weight *[see Drug Interactions (7.1)]*:

- Patients weighing less than 90 kg: from 120 mg to 240 mg
- Patients weighing 90 kg or greater: from 180 mg to 360 mg

After discontinuing a CYP3A inducer, resume the HERNEXEOS dose (7 to 14 days after discontinuing the CYP3A inducer) that was taken prior to initiating the CYP3A inducer.

3 DOSAGE FORMS AND STRENGTHS

60 mg tablets: yellow, oval, biconvex, film-coated tablets, debossed with "L6" on one side and the Boehringer Ingelheim company symbol on the other side. Each tablet contains 60 mg of zongertinib.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Hepatotoxicity

HERNEXEOS can cause severe and life-threatening hepatotoxicity, including drug induced liver injury. In the pooled safety population *[see Adverse Reactions (6.1)]*, based on adverse reaction data, hepatotoxicity occurred in 27% of patients treated with HERNEXEOS. Grade 3 drug induced liver injury occurred in 1.4% and Grade 4 in 0.3% of patients treated with HERNEXEOS. Grade 3 hepatic failure occurred in 0.3% of patients treated with HERNEXEOS.

Based on laboratory data, 37% of patients treated with HERNEXEOS experienced increased alanine aminotransferase (ALT), including 4.9% Grade 3 and 1% Grade 4. Increased aspartate aminotransferase (AST) occurred in 31% of patients treated with HERNEXEOS, including 3.8% Grade 3 and 0.7% Grade 4. Increased bilirubin occurred in 20% of patients treated with HERNEXEOS, including 1% Grade 3 and 0.3% Grade 4.

HERNEXEOS was interrupted for an adverse reaction of hepatotoxicity in 8% of patients, the dose was reduced in 3.8% and permanently discontinued in 1%.

Monitor liver function tests including ALT, AST, and total bilirubin at baseline prior to administration of HERNEXEOS, every 2 weeks during the first 12 weeks, and then monthly thereafter as clinically indicated, with more frequent testing in patients who develop transaminase elevations. Interrupt, reduce the dose, or permanently discontinue HERNEXEOS based on the severity of the adverse reaction *[see Dosage and Administration (2.3)]*.

5.2 Left Ventricular Dysfunction

HERNEXEOS can cause severe left ventricular dysfunction. Decreases in left ventricular ejection fraction (LVEF) have occurred with anti-HER2 therapies, including HERNEXEOS. Treatment with HERNEXEOS has

not been studied in patients with a history of clinically significant cardiac disease or LVEF less than 50% prior to initiation of treatment.

In the pooled safety population *[see Adverse Reactions (6.1)]*, LVEF decrease occurred in 6% of patients treated with HERNEXEOS, including 1.7% Grade 3. Two patients with Grade 3 LVEF decrease required permanent discontinuation of HERNEXEOS. The median time to onset of decreased LVEF was 12 weeks (range: 2.9 to 63 weeks).

Before initiating HERNEXEOS, evaluate LVEF and monitor at regular intervals during treatment and as clinically indicated. Interrupt, reduce the dose, or permanently discontinue HERNEXEOS based on the severity of the adverse reaction *[see Dosage and Administration (2.3)]*.

5.3 Interstitial Lung Disease/Pneumonitis

HERNEXEOS can cause severe and life-threatening interstitial lung disease (ILD)/pneumonitis.

In the pooled safety population *[see Adverse Reactions (6.1)]*, ILD/pneumonitis occurred in 2.1% of patients treated with HERNEXEOS. The median time to first onset of ILD/pneumonitis was 13 weeks (range: 1.4 to 65 weeks). One patient was able to resume therapy after resolution of pneumonitis. Two patients required permanent discontinuation and one patient died with unresolved pneumonitis > 30 days after discontinuing HERNEXEOS.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Interrupt, reduce the dose or permanently discontinue HERNEXEOS based on severity of confirmed ILD/pneumonitis *[see Dosage and Administration (2.3)]*.

5.4 Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, HERNEXEOS can cause fetal harm when administered to a pregnant woman. In an animal reproduction study, oral administration of zongertinib to pregnant rats during the period of organogenesis caused structural abnormalities and alterations to growth at maternal exposures ≥ 19 times the human exposure based on AUC at the recommended dose.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with HERNEXEOS and for 2 weeks after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Hepatotoxicity *[see Warnings and Precautions (5.1)]*
- Left Ventricular Dysfunction *[see Warnings and Precautions (5.2)]*
- Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The pooled safety population described in WARNINGS AND PRECAUTIONS reflects exposure to HERNEXEOS in 292 patients with unresectable or metastatic non-squamous NSCLC with HER2 (ERBB2)

mutations who received HERNEXEOS as a single agent at 120 mg orally once daily until disease progression or unacceptable toxicity in Beamion LUNG-1 *[see Clinical Studies (14)]*. Among 292 patients who received HERNEXEOS, 59% of patients were exposed for 6 months or longer and 28% were exposed for greater than one year. In this pooled safety population, the most common (≥ 20%) adverse reactions were diarrhea (54%), rash (28%), hepatotoxicity (27%), fatigue (25%), nausea (23%), musculoskeletal pain (21%), and upper respiratory tract infection (20%). The most common (≥ 2%) Grade 3 or 4 laboratory abnormalities were decreased lymphocytes (10%), increased alanine aminotransferase (6%), increased aspartate aminotransferase (4.5%), increased gamma glutamyl transferase (2.8%), decreased potassium (2.4%), and decreased neutrophils (2.4%).

Beamion LUNG-1

The safety of HERNEXEOS was evaluated in Beamion LUNG-1 in 177 patients with unresectable or metastatic non-squamous NSCLC with HER2 tyrosine kinase domain (TKD) mutations; 72 patients had not received prior treatment; 105 patients had received prior platinum-based chemotherapy, and out of those patients, 34 patients had received prior treatment with a HER2-directed antibody drug conjugate (ADC) *[see Clinical Studies (14)]*. Patients received HERNEXEOS as a single agent at 120 mg once daily until disease progression or unacceptable toxicity. Among patients who received HERNEXEOS, 74% were exposed for 6 months or longer and 42% were exposed for greater than one year. The median age of patients who received HERNEXEOS was 63 years (range 30 to 88), 61% were female, 41% White, 48% Asian, and 0.6% Black or African American; 11% had unknown race data; 3.4% were of Hispanic or Latino ethnicity; and 38% had an Eastern Cooperative Oncology Group (ECOG) performance score of 0 and 62% had an ECOG performance score of 1.

Serious adverse reactions occurred in 36% of patients receiving HERNEXEOS. Serious adverse reactions in ≥ 2% of patients included pulmonary embolism (4%), dyspnea (3.4%), pneumonia (2.8%), hepatotoxicity, pleural effusion, and pericardial effusion (2.3%). Fatal adverse reactions occurred in one patient (0.6%) who received HERNEXEOS, due to pneumonia.

Permanent discontinuation of HERNEXEOS due to an adverse reaction occurred in 6% of patients. Adverse reactions which resulted in permanent discontinuation of HERNEXEOS were hepatotoxicity, decreased ejection fraction, anemia, increased blood alkaline phosphatase, diarrhea, dyspnea, increased gamma-glutamyl transferase, hemoptysis, pericardial effusion, pneumonitis, and pyrexia.

Dosage interruption of HERNEXEOS due to an adverse reaction occurred in 34% of patients. Adverse reactions which required dosage interruption in ≥ 2% of patients were hepatotoxicity, decreased ejection fraction, diarrhea, COVID-19, rash, and vomiting.

Dose reductions of HERNEXEOS due to adverse reactions occurred in 9% of patients. Adverse reactions which required dose reductions in ≥ 1% of patients were hepatotoxicity, decreased ejection fraction, and diarrhea.

Tables 3 and 4 summarize adverse reactions and laboratory abnormalities observed in Beamion LUNG-1.

Table 3 Adverse Reactions (≥ 15%) in Patients with Non-Squamous NSCLC with HER2 TKD Mutations Who Received HERNEXEOS in Beamion LUNG-1

Adverse Reaction	**HERNEXEOS N = 177**	
	All Grades[1] %	**Grade 3 or 4 %**
Gastrointestinal Disorders		

Diarrhea*	56	2.8
Nausea	25	0.6
Stomatitis*	21	0
Skin and Subcutaneous Tissue Disorders		
Rash*	32	0.6
Nail disorders*	21	0.6
Pruritus	15	0
General Disorders		
Fatigue*	26	0.6
Headache	16	0.6
Respiratory, Thoracic and Mediastinal Disorders		
Cough*	23	0
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain*	23	2.3
Infections and Infestations		
Upper respiratory tract infections*	23	0

Events were graded using NCI CTCAE version 5.0.
[1]No Grade 4 or Grade 5 adverse reactions occurred.
*Grouped term.

Clinically relevant adverse reactions in < 15% of patients who received HERNEXEOS included vomiting, dyspnea, dysgeusia, and dry skin.

Table 4 Select Laboratory Abnormalities (≥ 20%) in Patients with Non-Squamous NSCLC with HER2 TKD Mutations Who Received HERNEXEOS in Beamion LUNG-1

Laboratory Parameter	**HERNEXEOS N = 177**	
	All Grades[1] %	**Grade 3 or 4 %**
Hematology		
Lymphocytes decreased	56	12
Hemoglobin decreased	37	1.1
Leukocytes decreased	35	1.1
Activated partial thromboplastin time increased	23	0
Platelets decreased	20	1.1
Chemistry		
Alanine aminotransferase increased	41	7
Aspartate aminotransferase increased	35	5
Creatinine kinase increased	28	1.7
Calcium decreased	28	0.6
Albumin decreased	26	0
Bilirubin increased	25	1.1
Lipase increased	25	0

Triglycerides increased	25	0
Sodium decreased	22	0.6
Bicarbonate decreased	22	0
Magnesium decreased	21	1.1
Potassium decreased	21	1.7
Alkaline phosphatase increased	20	1.7

Events were graded using NCI CTCAE version 5.0.
[1]No Grade 5 adverse reactions occurred.

7 DRUG INTERACTIONS

7.1 Effects of Other Drugs on HERNEXEOS

Avoid concomitant use of HERNEXEOS with strong CYP3A inducers. If concomitant use cannot be avoided, increase HERNEXEOS dose as recommended *[see Dosage and Administration (2.4)]*.

Zongertinib is a CYP3A substrate. Strong CYP3A inducers decrease zongertinib exposure *[see Clinical Pharmacology (12.3)]*, which may reduce effectiveness of HERNEXEOS.

7.2 Effects of HERNEXEOS on Other Drugs

BCRP Substrates

Avoid concomitant use of HERNEXEOS with certain BCRP substrates where minimal concentration changes may lead to serious adverse reactions. If coadministration cannot be avoided, monitor for increased adverse reactions and follow recommendations provided in the approved product labeling for the BCRP substrate. For other BCRP substrates, monitor for increased adverse reactions and adjust the dosages of those substrates as clinically appropriate.

Zongertinib is a BCRP inhibitor. HERNEXEOS increases exposure of BCRP substrates *[see Clinical Pharmacology (12.3)]*, which may increase the risk of adverse reactions related to these substrates.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on findings from animal studies and its mechanism of action *[see Clinical Pharmacology (12.1)]*, HERNEXEOS can cause fetal harm when administered to a pregnant woman. There are no available data on the use of HERNEXEOS in pregnant women to inform a drug-associated risk. Oral administration of zongertinib to pregnant rats during the period of organogenesis caused structural abnormalities and alterations to growth at maternal exposures ≥ 19 times the human exposure based on AUC at the recommended dose *[see Data]*. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

In an embryo-fetal development study, pregnant rats received oral doses of 10, 30, or 60 mg/kg/day of zongertinib during the period of organogenesis (gestation day 7 to 18). Zongertinib caused decreased fetal weights, delayed development of the urinary system, and kidney hydronephrosis at 60 mg/kg/day (approximately 19 times the human exposure based on AUC at the recommended dose). In an embryo-fetal development study in rabbits, there were no adverse embryo-fetal findings in pregnant animals administered

oral doses of zongertinib up to 120 mg/kg/day (2.4 times the human exposure based on AUC at the recommended dose) during the period of organogenesis (gestation day 6 to 19).

A literature-based assessment of the effects on reproduction demonstrated that mice expressing catalytically inactive HER2 die at mid-gestation due to cardiac dysfunction.

8.2 Lactation

Risk Summary

There are no data on the presence of zongertinib or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with HERNEXEOS and for 2 weeks after the last dose.

8.3 Females and Males of Reproductive Potential

Based on findings from animal studies and its mechanism of action, HERNEXEOS can cause embryo-fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*.

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating HERNEXEOS.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with HERNEXEOS and for 2 weeks after the last dose.

Infertility

Females

Based on findings from animal studies, HERNEXEOS may impair fertility in females. The effects in female animals were reversible *[see Nonclinical Toxicology (13.1)]*.

Males

Based on findings from animal studies, HERNEXEOS may impair fertility in males of reproductive potential. The effect on testes in animals was not reversible within a 4-week recovery period *[see Nonclinical Toxicology (13.1)]*.

8.4 Pediatric Use

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

8.5 Geriatric Use

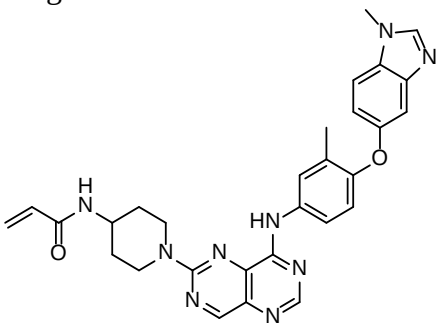
Of the 292 patients with non-squamous NSCLC with HER2 (ERBB2) mutations who received HERNEXEOS in clinical studies, 47% were 65 years of age and older and 13% were 75 years and older. No overall differences in safety or effectiveness of HERNEXEOS were observed between older and younger adult patients.

10 OVERDOSAGE

Overdose in one patient who ingested 600 mg of HERNEXEOS resulted in nausea and vomiting.

11 DESCRIPTION

HERNEXEOS tablets for oral administration contain zongertinib, a kinase inhibitor. The chemical name of zongertinib is 2-Propenamide, *N*-[1-[8-[[3-methyl-4-[(1-methyl-1*H*-benzimidazol-5-yl)oxy]phenyl] amino]pyrimido[5,4-*d*]pyrimidin-2-yl]-4-piperidinyl]-. Its molecular formula is $C_{29}H_{29}N_9O_2$ and the molecular weight is 535.6. The structural formula is:



Zongertinib is a yellow to dark yellow or orange solid. Zongertinib is slightly soluble at pH 1.2, and practically insoluble at pHs 3.6, 4.5, 5.4 and 6.8.

Each film-coated tablet of HERNEXEOS contains 60 mg of zongertinib and the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, mannitol, microcrystalline cellulose, and sodium stearyl fumarate. In addition, the film-coating contains the following inactive ingredients: ferric oxide (yellow), glycerol mono and dicaprylocaprate, polyvinyl alcohol, sodium lauryl sulfate, talc, and titanium dioxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Zongertinib is a kinase inhibitor of human epidermal growth factor receptor 2 (HER2). In vitro, zongertinib inhibited phosphorylation of HER2, downstream signaling of HER2 (phosphorylation of ERK), and proliferation of lung cancer cells harboring HER2 tyrosine kinase domain activating mutations. In vivo, zongertinib demonstrated anti-tumor activity in mouse xenograft models of NSCLC harboring HER2 tyrosine kinase domain activating mutations.

12.2 Pharmacodynamics

The exposure-response relationship and time-course of pharmacodynamic response of zongertinib have not been fully characterized.

Cardiac Electrophysiology

At 2.6 times the mean maximal concentration provided by the recommended dose of 120 mg, a mean increase in the QTc interval > 20 ms was not observed.

12.3 Pharmacokinetics

Zongertinib pharmacokinetics were observed at steady state in patients with advanced or metastatic solid tumors with HER2 aberrations at the approved recommended dosage and are presented as geometric mean (CV%), unless otherwise specified.

Zongertinib maximum concentration ($C_{max,ss}$) is 3 (37%) µmol/L and the total systemic exposure (AUC) is 34 (34%) µmol*h/L following HERNEXEOS 120 mg orally daily. Zongertinib C_{max} and AUC increase in an approximately dose proportional manner across the dose range of 60 mg (0.5 times the approved recommended dosage) to 360 mg (3 times the approved recommended dosage). Zongertinib accumulation is approximately

1.5-fold for AUC and 1.3-fold for C_{max} at the approved recommended dosage. Steady state is achieved within 2.5 days.

Absorption
Zongertinib median (min, max) time to maximum plasma concentration (T_{max}) is approximately 2 hours (min, max: 2, 6 hours). Zongertinib absolute oral bioavailability is 76%.

Effect of Food
No clinically significant differences in zongertinib C_{max} and AUC were observed following administration of a single 240 mg dose (2 times the approved recommended dose) with a high-fat meal (approximately 1,000 calories, approximately 50% fat).

Distribution
Zongertinib plasma protein binding is > 99%. The apparent (oral) volume of distribution is 118 L (29%).

Elimination
Zongertinib effective half-life is 12 hours (21%) with an apparent (oral) clearance of 115 mL/min (31%).

Metabolism
Based on in vitro metabolite profiling, CYP-mediated oxidation pathways represent 48% to 62% (mainly CYP3A4 and CYP3A5), glucuronidation 13% to 25% (mainly UGT1A4), and glutathione conjugation 13% to 26% of total hepatic metabolism. Unchanged zongertinib represented the majority (75%) of total radioactivity in plasma.

Excretion
After a single oral dose of radiolabeled zongertinib 60 mg to healthy participants, approximately 93% of the dose was recovered in feces (31% unchanged) and 1.3% in urine (0.2% unchanged).

Specific Populations
The apparent volume of distribution and clearance of zongertinib increase with increasing body weight (34 to 122 kg).

No clinically significant differences in the pharmacokinetics of zongertinib were observed based on age (30 to 88 years), sex, race (36% White, 49% Asian, 1.3% Black/African American), eGFR 60 to < 90 mL/min, or mild (defined as Child-Pugh A; AST > ULN and total bilirubin ≤ ULN; or total bilirubin > 1 to 1.5x ULN and any AST) and moderate (Child-Pugh B) hepatic impairment. The effect of eGFR 15 to < 60 mL/min, end-stage renal disease (eGFR < 15 mL/min) and severe hepatic impairment on the pharmacokinetics of zongertinib has not been studied.

Drug Interaction Studies
CYP3A Inducers: Zongertinib AUC decreased by 63% and C_{max} decreased by 43% following concomitant use of carbamazepine (strong CYP3A inducer) 600 mg once daily for 7 days. The effect of concomitant use of moderate CYP3A inducers on zongertinib C_{max} and AUC are unknown.

BCRP Substrates: Rosuvastatin (BCRP substrate) C_{max} increased 3-fold and AUC 2.3-fold following concomitant use of HERNEXEOS 120 mg daily for 12 days.

Other Drugs: No clinically significant differences in zongertinib pharmacokinetics were observed when used concomitantly with strong CYP3A, P-gp, BCRP inhibitors and rabeprazole (proton pump inhibitor).

No clinically significant differences in the pharmacokinetics of the following were observed when used concomitantly with zongertinib: midazolam (a CYP3A substrate), dabigatran (a P-gp substrate), metformin (a OCT2 and MATE1/2-K substrate), or repaglinide (a sensitive CYP2C8 substrate).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies have not been conducted with zongertinib.

Mutagenesis

Zongertinib was not mutagenic in an in vitro bacterial reverse mutation (Ames) assay. Zongertinib was not genotoxic in an in vivo rat bone marrow micronucleus test and did not induce DNA breaks in a comet assay in liver or duodenum.

Impairment of Fertility

Dedicated animal fertility studies have not been conducted with zongertinib. In a 13-week repeat-dose toxicity study in rats, oral administration of zongertinib induced dose-dependent vacuolation in the testis at doses ≥ 10 mg/kg/day (≥ 5.7 times the human exposure based on AUC at the recommended dose), atrophy in the prostate gland at doses ≥ 30 mg/kg/day (≥ 8.4 times the human exposure based on AUC at the recommended dose), and atrophy in the uterus and hyperplasia/hyperkeratosis of the cervix and vagina at a dose of 90 mg/kg/day (approximately 17 times the human exposure based on AUC at the recommended dose). Findings in reproductive organs in female rats and prostate gland atrophy in male rats were reversible following a 4-week recovery period. Vacuolation in the testis of male rats was not reversible within a 4-week recovery period.

13.2 Animal Toxicology and/or Pharmacology

In a 4-week repeat-dose toxicology study in dogs, oral administration of zongertinib induced lesions of the oral mucosa (hard palate, buccal mucosa, tongue, lips) at doses ≥ 10 mg/kg/day (≥ 0.3 times the human exposure based on AUC at the recommended dose), which correlated with histologic erosion/ulcer and impaired food consumption. These findings were not present following a 4-week recovery period.

14 CLINICAL STUDIES

HERNEXEOS was evaluated in Beamion LUNG-1 (NCT04886804), a single arm, open-label, multi-center, multi-cohort trial. Eligible patients were required to have unresectable or metastatic NSCLC with HER2 (ERBB2) mutations. Patients with stable brain metastases were eligible to enroll. The study excluded patients who had a history of non-infectious interstitial lung disease/pneumonitis.

Patients received HERNEXEOS 120 mg orally once daily until disease progression or unacceptable toxicity. The major efficacy outcome measures were objective response rate (ORR) and duration of response (DOR) by Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 as assessed by blinded independent central review (BICR).

Previously Untreated Unresectable or Metastatic Non-Squamous NSCLC

The efficacy population included 72 patients with unresectable or metastatic, non-squamous NSCLC with HER2 (ERBB2) tyrosine kinase domain (TKD) mutations based on prospective local testing, who had not received prior systemic therapy for advanced disease. Of those, tumor tissue samples from 60% (43/72) of patients were retrospectively tested using Oncomine™ Dx Target Test (Life Technologies Corporation, Tissue-

test). While 86% (37/43) of samples were positive for HER2 (ERBB2) TKD mutations; 14% (6/43) were unevaluable.

The baseline demographic and disease characteristics of the efficacy population were: 67 years (range: 35 to 88); 50% female, 47% Asian, 42% White, 1.4% Black or African American; 10% had unknown race data; 6% were of Hispanic or Latino ethnicity; 44% Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 and 56% ECOG PS 1; 65% never smoked; 100% had metastatic disease; and 31% had brain metastases.

Efficacy results are summarized in Table 5.

Table 5 Efficacy Results for Beamion LUNG-1 in Previously Untreated Non-Squamous NSCLC

Efficacy Parameter	**HERNEXEOS N = 72**
Objective Response Rate (ORR), % (95% CI)[1]	76 (65, 85)
Complete response, %	11
Partial response, %	65
Duration of Response (DOR)	**N = 55**
Range, months	1.4, 18+
DOR ≥ 6 months,[2] %	64
DOR ≥ 12 months,[2] %	44

Abbreviation: CI = Confidence Interval, +: Ongoing response.
[1]Based on Wilson confidence interval.
[2]Based on observed duration of response.

Previously Treated Unresectable or Metastatic Non-Squamous NSCLC

The efficacy population included 71 patients with unresectable or metastatic, non-squamous NSCLC with HER2 (ERBB2) TKD mutations based on prospective local testing. Of those, tumor tissue samples from 52% (37/71) of patients were retrospectively tested using Oncomine™ Dx Target Test (Life Technologies Corporation, Tissue-test). While 84% (31/37) of samples were positive for HER2 (ERBB2) TKD mutations, 2.7% (1/37) did not have HER2 (ERBB2) TKD mutations identified, and 13.5% (5/37) were unevaluable.

The baseline demographic and disease characteristics of the efficacy population were: 62 years (range: 30 to 80); 70% female, 55% Asian, 35% White, 0% Black or African American; 10% had unknown race data; 1.4% were of Hispanic or Latino ethnicity; 39% Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 and 61% ECOG PS 1; 65% never smoked; 100% metastatic disease; and 37% with brain metastases. The median number of prior therapies was 1 (range: 1 to 10); 100% of patients had prior platinum therapy and 78% had prior treatment with anti-PD-1/PD-L1 antibody. No patient had received previous treatment with a HER2-targeted tyrosine kinase inhibitor (TKI) or HER2-targeted antibody-drug conjugate (ADC).

Efficacy results are summarized in Table 6.

Table 6 Efficacy Results for Beamion LUNG-1 in Previously Treated Non-Squamous NSCLC

Efficacy Parameter	**HERNEXEOS N = 71**
Objective Response Rate (ORR), % (95% CI)[1]	75 (63, 83)

Complete response, %	6
Partial response, %	69
Duration of Response (DOR)	**N = 53**
Range, months	1.3+, 15+
DOR ≥ 6 months,[2] %	58

Abbreviation: CI = Confidence Interval, +: Ongoing response.
[1]Based on Wilson confidence interval.
[2]Based on observed duration of response.

Among the 71 patients, 5 patients had measurable CNS metastases at baseline as assessed by BICR and had not received radiation therapy to the brain within 2 months prior to treatment with HERNEXEOS. Based on Response Assessment in Neuro-Oncology Brain Metastases (RANO-BM) criteria per BICR, responses were observed in 3 patients.

HERNEXEOS was also evaluated in 34 patients with unresectable or metastatic HER2 (ERBB2) TKD mutation-positive non-squamous NSCLC who had received previous treatment with platinum-based chemotherapy and a HER2-targeted ADC. Eligibility criteria were otherwise similar to the efficacy population described above. The median age was 58 years (range: 31 to 85); 65% female, 35% Asian, 50% White, 0% Black or African American; 15% had unknown race data; and 2.9% were of Hispanic or Latino ethnicity. Baseline ECOG performance status was 0 (21%) or 1 (79%); 65% never smoked; 100% of patients had metastatic disease and 74% had brain metastases. The median number of prior therapies was 3 (range: 1 to 8); 100% of patients had prior platinum therapy and 77% had prior treatment with anti-PD-1/PD-L1 antibody; 2.9% of patients had received previous treatment with a HER2-targeted TKI. Confirmed ORR by RECIST v1.1 based on BICR was 44% (95% CI 29, 61), with 2.9% of patients having a complete response. Median DOR was 5.4 months (95% CI 2.8, not estimable), and 27% of responders had an observed DOR ≥ 6 months.

16 HOW SUPPLIED/STORAGE AND HANDLING

60 mg tablets: yellow, oval, biconvex, film-coated, debossed with “L6” on one side and the Boehringer Ingelheim company symbol on the other side. They are packaged in a bottle containing two silica gel desiccants and with a child-resistant closure, available as follows:

Carton containing one bottle of 30 tablets each	NDC: 0597-9257-59
Carton containing one bottle of 60 tablets each	NDC: 0597-9257-86

Storage and Handling

Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Store in the original container to protect from moisture. Keep the bottle tightly closed. Do not remove the desiccants. Once opened, use within 3 months. Discard any unused tablets 3 months after opening the bottle.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Hepatotoxicity

Inform patients that HERNEXEOS can cause severe and life-threatening hepatotoxicity and that they will need to undergo lab tests to monitor liver enzymes during treatment *[see Warnings and Precautions (5.1)]*. Advise patients to immediately contact their healthcare provider for signs and symptoms of hepatotoxicity.

Left Ventricular Dysfunction
Inform patients that HERNEXEOS can cause severe left ventricular dysfunction. Advise patients to immediately contact their healthcare provider for new or worsening cardiovascular symptoms *[see Warnings and Precautions (5.2)]*.

Interstitial Lung Disease (ILD)/Pneumonitis
Inform patients that HERNEXEOS can cause severe or life-threatening ILD/pneumonitis. Advise patients to immediately contact their healthcare provider for new or worsening respiratory symptoms *[see Warnings and Precautions (5.3)]*.

Diarrhea
Inform patients that HERNEXEOS can cause diarrhea. Advise patients to immediately contact their healthcare provider for new or worsening diarrhea *[see Adverse Reactions (6.1)]*.

Embryo-Fetal Toxicity
Advise females of reproductive potential of the potential risk to a fetus. Advise females to inform their healthcare provider of a known or suspected pregnancy. Advise females of reproductive potential to use effective contraception during treatment with HERNEXEOS and for 2 weeks after the last dose *[see Warnings and Precautions (5.4) and Use in Specific Populations (8.1, 8.3)]*.

Lactation
Advise women not to breastfeed during treatment with HERNEXEOS and for 2 weeks after the last dose *[see Use in Specific Populations (8.2)]*.

Infertility
Advise females and males of reproductive potential that HERNEXEOS may impair fertility *[see Use in Specific Populations (8.3)]*.

Administration Instructions
Instruct patients weighing less than 90 kg to take two 60 mg tablets once daily to achieve a complete 120 mg dose and instruct patients weighing 90 kg or greater to take three 60 mg tablets once daily to achieve a complete 180 mg dose *[see Dosage and Administration (2.2)]*. HERNEXEOS film-coated tablets can be taken with or without food *[see Clinical Pharmacology (12.3)]*. Instruct patients to swallow HERNEXEOS tablets whole with water. Do not split, crush, or chew tablets.

Inform patients that if they miss a dose of HERNEXEOS within 12 hours, they should take it as soon as they remember. If a dose is missed by more than 12 hours, the patient should skip the missed dose and wait until the next scheduled dose *[see Dosage and Administration (2.2)]*.

If a dose is vomited, do not take an additional dose. Take the next dose at the regularly scheduled time.

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Patient Information
HERNEXEOS® (her-nex-ee-ose)
(zongertinib tablets)

What is HERNEXEOS?

HERNEXEOS is a prescription medicine used to treat adults with a type of lung cancer called non-squamous non-small cell lung cancer (NSCLC) that:

- cannot be removed by surgery or that has spread to other parts of your body (metastatic), **and**
- has a certain mutation in the human epidermal growth factor receptor 2 (HER2) gene.

Your healthcare provider will perform a test to make sure HERNEXEOS is right for you.

It is not known if HERNEXEOS is safe and effective in children.

Before taking HERNEXEOS, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have heart problems
- have lung or breathing problems other than lung cancer
- are pregnant or plan to become pregnant. HERNEXEOS can harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with HERNEXEOS.
  - Use an effective form of birth control (contraception) during treatment with HERNEXEOS and for 2 weeks after your last dose.
  - Talk to your healthcare provider about birth control methods that might be right for you during this time.
  - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with HERNEXEOS.
- are breastfeeding or plan to breastfeed. It is not known if HERNEXEOS passes into your breastmilk. Do not breastfeed during treatment and for 2 weeks after your last dose of HERNEXEOS.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. HERNEXEOS may affect the way other medicines work, and other medicines may affect how HERNEXEOS works.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take HERNEXEOS?

- Take HERNEXEOS exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose if needed. Do not change your dose or stop taking HERNEXEOS unless your healthcare provider tells you to.
- Take HERNEXEOS 1 time a day, with or without food.
- Swallow HERNEXEOS tablets whole with water. Do not split, crush, or chew tablets.
- If you miss a dose of HERNEXEOS, take it as soon as you remember within 12 hours. If you missed your dose by more than 12 hours, skip the missed dose and take your next dose at your next scheduled time.
- If you vomit after taking a dose of HERNEXEOS, do not take an extra dose. Take your next dose at your regularly scheduled time.
- If you take too much HERNEXEOS, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of HERNEXEOS?

HERNEXEOS may cause serious side effects, including:

- **liver problems.** Liver problems are common with HERNEXEOS and can be severe and life-threatening. Your healthcare provider will do blood tests to check your liver function before you start taking HERNEXEOS and during your treatment. Tell your healthcare provider right away if you develop any signs and symptoms of liver problems, including:
  - yellowing of your skin or the white part of your eyes (jaundice)
  - dark or brown (tea colored) urine
  - pain on the upper right side of your stomach
  - bleeding or bruising more easily than normal
  - feeling very tired
  - loss of appetite
  - nausea or vomiting

area (abdomen)

- **heart problems that may affect your heart's ability to pump blood.** HERNEXEOS can cause severe heart problems. Your healthcare provider will do tests to check your heart function before you start taking HERNEXEOS and during treatment. Tell your healthcare provider right away if you have any new or worsening symptoms of heart problems, including:
  - o feeling like your heart is pounding or racing
  - o dizziness
  - o tiredness
  - o feeling lightheaded
  - o shortness of breath
  - o loss of consciousness
  - o coughing
  - o swelling of your legs, ankles or feet
- **lung problems.** HERNEXEOS can cause lung problems that are severe or life-threatening. Tell your healthcare provider right away if you have any new or worsening symptoms of lung problems, including trouble breathing, shortness of breath, cough, or fever.

Your healthcare provider may temporarily stop, decrease your dose, or permanently stop treatment with HERNEXEOS if you have serious side effects.

The most common side effects of HERNEXEOS include:

- diarrhea. HERNEXEOS can cause severe diarrhea. Tell your healthcare provider right away if you have new or worsening diarrhea.
- rash
- liver problems
- feeling tired
- nausea
- muscle and joint pain
- upper respiratory tract infection

The most common severe abnormal blood tests include decreased white blood cell count, increased liver function tests and decreased potassium levels.

HERNEXEOS may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of HERNEXEOS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store HERNEXEOS?

- Store HERNEXEOS at room temperature between 68°F to 77°F (20°C to 25°C).
- Store HERNEXEOS tablets in the original bottle.
- Keep the HERNEXEOS bottle tightly closed.
- The HERNEXEOS bottle contains two desiccants to help keep your tablets dry (protect from moisture). Do not remove the desiccants from the container after opening. Do not eat or swallow the desiccants.
- HERNEXEOS comes in a child-resistant bottle.
- HERNEXEOS must be used within 3 months of first opening the bottle. Throw away (discard) any unused tablets 3 months after opening the bottle.

Keep HERNEXEOS and all medicines out of the reach of children.

General information about the safe and effective use of HERNEXEOS.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use HERNEXEOS for any condition for which it was not prescribed. Do not give HERNEXEOS to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about HERNEXEOS that is written for health professionals.

What are the ingredients in HERNEXEOS?

Active ingredient: zongertinib

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, mannitol, microcrystalline cellulose, and sodium stearyl fumarate. The film-coating contains ferric oxide (yellow), glycerol mono and dicaprylocaprate, polyvinyl alcohol, sodium lauryl sulfate, talc, and titanium dioxide.

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For more information about HERNEXEOS, including the current prescribing information and Patient Information, go to **www.hernexeos.com**, scan the code, or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: FEB 2026