TEPMETKO® (tepotinib) Product Information

INDICATION:

TEPMETKO is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (*MET*) exon 14 skipping alterations.

About TEPMETKO:

TEPMETKO is highly selective for *MET*ex14 with early durable efficacy and a manageable adverse event profile.[1]

National Comprehensive Cancer Network® (NCCN®) Recommendation:

Tepotinib is recommended by the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) as a Category 2A and preferred systemic therapy option in the first-line and subsequent-line* settings for patients with metastatic *MET*ex14+ NSCLC.[2,†,‡,§]

Dosing and Administration:

FDA-approved administration is oral once-daily, with one-step dose reduction in the case of tolerability management.[1,||]

Distribution:

TEPMETKO has a limited distribution model allowing in-office dispensing or to be filled by the specialty pharmacy Biologics. Further details are listed under Specialty Distributors.

Supplied and Marketed By:

EMD Serono, Inc.
Rockland, MA 02370
U.S.A.

1-888-398-4567
www.emdserono.com/us-en
www.TEPMETKO.com

Product Expiration:

The expiration is printed on each box and blister card.

Customer Service:

1-888-398-4567 | us.customerservice@emdserono.com

For information and instructions regarding product ordering or returns, please contact your Specialty Distributor or EMD Serono Customer Service at 1-888-398-4567.

Access and Reimbursement Support for Eligible Patients:

CoverOne

Phone: 1-844-662-3631
Fax: 1-844-501-0062
www.CoverOne.com

Product Information:

Product Name:	TEPMETKO
Established Name:	tepotinib
Description[1]:	TEPMETKO (tepotinib) tablets: 225 mg tepotinib, white-pink, oval, biconvex film-coated tablet with embossment "M" on one side and plain on the other side
National Drug Code (NDC)[1]:	**44087-5000-3** Box of 30 tablets: 3 blister cards each containing 10 tablets **44087-5000-6** Box of 60 tablets: 6 blister cards each containing 10 tablets

Dosage and Administration Highlights[1]:

Select patients for treatment with TEPMETKO based on the presence of *MET* exon 14 skipping alterations in plasma or tumor specimens. Testing for the presence of *MET* exon 14 skipping alterations in plasma specimens is recommended only in patients for whom a tumor biopsy cannot be obtained. If an alteration is not detected in a plasma specimen, re-evaluate the feasibility of biopsy for tumor tissue testing. An FDA-approved test for detection of *MET* exon 14 skipping alterations in NSCLC for selecting patients for treatment with TEPMETKO is not available.

The recommended dosage of TEPMETKO is 450 mg orally once daily with food until disease progression or unacceptable toxicity.

TEPMETKO can be dissolved and administered to patients who have difficulty swallowing solids and/or have a naso-gastric tube.

Storage and Handling[1]:

Store TEPMETKO at 20°C-25°C (68°F-77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP-NF Controlled Room Temperature]. Store in original package.

IMPORTANT SAFETY INFORMATION:

TEPMETKO can cause **interstitial lung disease (ILD)/pneumonitis**, which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold TEPMETKO in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified. ILD/pneumonitis occurred in 2% of patients treated with TEPMETKO, with one patient experiencing a Grade 3 or higher event; this event resulted in death.

Please see additional Important Safety Information on next page and full Prescribing Information.

FDA=US Food and Drug Administration.
*If *MET*ex14 skipping mutation inhibitors have not previously been given.
†See the NCCN Guidelines® for detailed recommendations, including other preferred options.
‡The NCCN Guidelines for NSCLC provide recommendations for certain individual biomarkers that should be tested and recommend testing techniques but do not endorse any specific commercially available biomarker assays or commercial laboratories.
§Note that *Category 2A* and *Preferred* are two separate recommendations.
||Recommended dose is 450 mg once daily with food until disease progression or unacceptable toxicity. See full Prescribing Information for more Dosing Information.

TEPMETKO® (tepotinib) 225 mg Tablets

Specialty Distributors:

Oncology Supply
2801 Horace Shepard Drive
Dothan, AL 36303
Phone: 1-800-633-7555
customerservice@oncologysupply.com

McKesson Plasma and Biologics
2615 Medical Center Parkway, Ste 1580
Murfreesboro, TN 37129
Phone: 1-877-625-2566
Fax: 1-888-752-7626
mpborders@mckesson.com
www.connect.mckesson.com

Cardinal Health Specialty Solutions
15 Ingram Boulevard
La Vergne, TN 37086
Hospitals: 1-866-677-4844
Physician office: 1-866-300-3838

McKesson Specialty Health
401 Mason Road
La Vergne, TN 37086
Phone: 1-800-482-6700
Fax: 1-800-289-9298
msh-customercare@mckesson.com

ASD Healthcare
3101 Gaylord Parkway
Frisco, TX 75034
Phone: 1-800-746-6273
Fax: 1-800-547-9413
asd.customerservice@asdhealthcare.com

Specialty Pharmacy:

Biologics Specialty Pharmacy
11800 Weston Parkway, Cary, NC 27513
Phone: 1-800-850-4306 – Option 2
Fax: 1-800-823-4506
Hours: 8AM-8PM EST Mon-Fri, 24/7
www.biologicsinc.com

IMPORTANT SAFETY INFORMATION (continued):

TEPMETKO can cause **hepatotoxicity**, which can be fatal. Monitor liver function tests (including alanine aminotransferase [ALT], aspartate aminotransferase [AST], and total bilirubin) prior to the start of TEPMETKO, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or total bilirubin. Based on the severity of the adverse reaction, withhold, dose reduce, or permanently discontinue TEPMETKO. Increased ALT/increased AST occurred in 18% of patients treated with TEPMETKO. Grade 3 or 4 increased ALT/AST occurred in 4.7% of patients. A fatal adverse reaction of hepatic failure occurred in one patient (0.2%). The median time-to-onset of Grade 3 or higher increased ALT/AST was 47 days (range 1 to 262).

TEPMETKO can cause **pancreatic toxicity** in the form of elevations in amylase and lipase levels. Increased amylase and/or lipase occurred in 13% of patients, with Grade 3 and 4 increases occurring in 5% and 1.2% of patients, respectively. Monitor amylase and lipase levels at baseline and regularly during treatment with TEPMETKO and temporarily withhold, dose reduce, or permanently discontinue based on severity of the adverse event.

TEPMETKO can cause **embryo-fetal toxicity**. Based on findings in animal studies and its mechanism of action, TEPMETKO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential or males with female partners of reproductive potential to use effective contraception during treatment with TEPMETKO and for one week after the last dose.

Avoid concomitant use of TEPMETKO with certain **P-gp substrates** where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, reduce the P-gp substrate dosage if recommended in its approved product labeling.

Fatal adverse reactions occurred in one patient (0.3%) due to pneumonitis, one patient (0.3%) due to hepatic failure, one patient (0.3%) due to dyspnea from fluid overload, one patient (0.3%) due to pneumonia, one patient (0.3%) due to sepsis, and one patient (0.3%) from unknown cause.

Serious adverse reactions occurred in 51% of patients who received TEPMETKO. Serious adverse reactions in >2% of patients included pleural effusion (6%), pneumonia (6%), edema (5%), general health deterioration (3.8%), dyspnea (3.5%), musculoskeletal pain (2.9%), and pulmonary embolism (2.2%).

The most common adverse reactions (≥20%) in patients who received TEPMETKO were edema (81%), nausea (31%), fatigue (30%), musculoskeletal pain (30%), diarrhea (29%), dyspnea (24%), rash (21%), and decreased appetite (21%).

Clinically relevant adverse reactions in <10% of patients who received TEPMETKO included ILD/pneumonitis, fever, dizziness, pruritus, and headache.

Selected laboratory abnormalities (≥20%) from baseline in patients receiving TEPMETKO in descending order were: decreased albumin (81%), increased creatinine (60%), decreased lymphocytes (57%), increased alkaline phosphatase (ALP) (52%), increased ALT (50%), increased AST (40%), decreased sodium (36%), decreased hemoglobin (31%), increased gamma-glutamyltransferase (GGT) (29%), increased potassium (26%), increased amylase (25%), decreased leukocytes (25%), decreased platelets (24%), and increased lipase (21%).

The most common Grade 3-4 laboratory abnormalities (≥2%) in descending order were: decreased lymphocytes (15%), decreased albumin (9%), decreased sodium (9%), increased GGT (6%), increased amylase (5%), increased lipase (5%), increased ALT (4.9%), increased AST (3.6%), and decreased hemoglobin (3.6%).

Please see full Prescribing Information.

References: 1. TEPMETKO® (tepotinib) [prescribing information]. EMD Serono, Inc., Rockland, MA; 2024. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.7.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed June 26, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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(tepotinib) 225 mg Tablets