

FIRST TIME GENERIC APPROVAL

Brand Name	Pylera®
Generic Name	bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride
Drug Manufacturer	Par Pharmaceutical, Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

March 6, 2023

LAUNCH DATE

March 8, 2023

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 205770

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride capsules are a combination of metronidazole, a nitroimidazole antimicrobial, tetracycline, a tetracycline class antimicrobial and bismuth subcitrate potassium, indicated for use, in combination with omeprazole, for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride capsules and other antibacterial drugs, bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride capsules should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

MECHANISMS OF ACTION

Bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride is a combination of antibacterial agents (metronidazole and tetracycline hydrochloride) and bismuth subcitrate potassium. Tetracycline hydrochloride interacts with the 30S subunit of the bacterial ribosome and inhibits protein synthesis. Metronidazole's antibacterial mechanism of action in an anaerobic environment is not fully understood but a possible mechanism includes reduction by intracellular electron transport proteins after entry into the organism.

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Because of this alteration to the metronidazole molecule, a concentration gradient is created and maintained which promotes the drug's intracellular transport. Presumably, free radicals are formed which, in turn, react with cellular components resulting in death of bacteria. The antibacterial action of bismuth salts is not well understood.

Antimicrobial Activity

Bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride plus omeprazole therapy has been shown to be active against most isolates of *Helicobacter pylori* both in vitro and in clinical infections.

DOSE FORM AND STRENGTH

Each capsule of bismuth subcitrate potassium, metronidazole and tetracycline hydrochloride capsules contains:

- 140 mg of bismuth subcitrate potassium
- 125 mg metronidazole, USP
- 125 mg of tetracycline hydrochloride, USP

DOSE & ADMINISTRATION

Administer 3 capsules 4 times a day (after meals and at bedtime) for 10 days. Take with omeprazole 20 mg twice daily (after the morning and evening meals).