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Cipla receives final approval for Esomeprazole

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It is the first company to file for the 10mg strength

Cipla has announced that it has received final approval for its Abbreviated New Drug Application (ANDA) for Esomeprazole for Oral Suspension 10mg, 20mg and 40mg from the United States Food and Drug Administration (USFDA).

It is the first company to file for the 10mg strength.

Esomeprazole for Oral Suspension 10mg, 20mg and 40mg is AB-rated generic therapeutic equivalent version of AstraZeneca Pharmaceutical's Nexium.

It is a proton pump inhibitor indicated for the following:

- Treatment of gastroesophageal reflux disease (GERD).
- Risk reduction of NSAID-associated gastric ulcer.
- H. pylori eradication to reduce the risk of duodenal ulcer recurrence.
- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

According to IQVIA (IMS Health), Nexium and its generic equivalents had US sales of approximately $70M for the 12-month period ending November 2019.

The product is available for shipping immediately.