

Sandoz ships first medicine in collaboration with Civica Rx to supply US hospitals

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- *Pantoprazole is the first Sandoz medicine to ship to Civica Rx to supply its member hospitals as part of a five-year agreement to reduce supply shortages*
- *Collaboration is being expanded to include additional medicine used as part of treatment for COVID-19 patients*
- *As a worldwide leader in generic and biosimilar medicines, Sandoz is committed to supporting efforts to deliver vital generic medicines to patients*

Princeton, New Jersey, NOVEMBER 2, 2020 — Sandoz Inc. today announced that it has shipped pantoprazole sodium for injection, 40 mg to Civica Rx to supply the hospitals it serves as part of a multiyear collaboration to help reduce supply shortages, with several other medicines on the way before the end of the year.

Pantoprazole is the first Sandoz medicine to ship to Civica since entering into the agreement in July. It is a proton pump inhibitor indicated in adults for the short-term treatment (7 to 10 days) of gastroesophageal reflux disease (GERD), associated with a history of erosive esophagitis¹.

Sandoz previously announced it will supply six injectable medicines under the Civica private label to its 1,200 US hospitals. The agreement is being expanded to include an additional medicine to regulate blood pressure, which is frequently used to treat COVID-19 patients in hospitals.

“Our collaboration with Civica is providing certainty for hospitals, doctors and patients who are too often frustrated by shortages of medicines. This is especially important as healthcare providers continue to manage the COVID-19 pandemic,” said Carol Lynch, President, Sandoz Inc. “We are committed to ensuring our medicines are there for the patients who need them when they need them.”

Civica, a non-profit, was founded in 2018 by leading US hospital systems concerned about generic drug shortages and philanthropic organizations passionate about improving healthcare. To date, more than 50 health systems are Civica members, representing more than 1,200 US hospitals and approximately 30 percent of all licensed US hospital beds including acute care.

“Within a year since our first medication was administered in a hospital ICU, we’ve been able to help millions of patients,” said Martin VanTrieste, president and CEO of Civica.

“With Sandoz, we look forward to helping millions more by providing critical medicines that have often been in short supply.”

INDICATIONS AND USAGE

Pantoprazole sodium is a proton pump inhibitor (PPI) indicated in adults for the following:

- Short-term treatment (7 to 10 days) of gastroesophageal reflux disease (GERD) associated with a history of Erosive Esophagitis (EE).
- Pathological hypersecretion conditions including Zollinger-Ellison (ZE) Syndrome.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Patients with a known hypersensitivity to any component of the formulation or to substituted benzimidazoles.
- Patients receiving rilpivirine-containing products.

WARNINGS AND PRECAUTIONS

- **Gastric Malignancy:** In adults, symptomatic response to therapy with pantoprazole sodium for injection does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing.
- **Hypersensitivity and Severe Skin Reactions:** Anaphylaxis and other serious reactions such as erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis (TEN) have been reported.
- **Injection Site Reactions:** Thrombophlebitis is associated with the administration of intravenous pantoprazole.
- **Potential Exacerbation of Zinc Deficiency:** Consider zinc supplementation in patients who are prone to zinc deficiency. Caution should be used when other EDTA containing products are also co-administered intravenously.
- **Acute Interstitial Nephritis:** Observed in patients taking PPIs.
- **Clostridium difficile-Associated Diarrhea:** PPI therapy may be associated with increased risk.

- **Bone Fracture:** Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine.
- **Cutaneous and Systemic Lupus Erythematosus:** Mostly cutaneous; new onset or exacerbation of existing disease; discontinue pantoprazole sodium for injection and refer to specialist for evaluation.
- **Hepatic Effects:** Elevations of transaminases observed.
- **Hypomagnesemia:** Reported rarely with prolonged treatment with PPIs.
- **Fundic Gland Polyps:** Risk increases with long-term use, especially beyond one year. Use the shortest duration of therapy.

ADVERSE REACTIONS

Most common adverse reactions (>2%) are: headache, diarrhea, nausea, abdominal pain, vomiting, flatulence, dizziness, and arthralgia.

DRUG INTERACTIONS

- **Antiretrovirals:** Decreased exposure of some antiretroviral drugs (e.g., rilpivirine, atazanavir, and nelfinavir) when used concomitantly with pantoprazole may reduce antiviral effect and promote the development of drug resistance. Increased exposure of other antiretroviral drugs (e.g., saquinavir) when used concomitantly with pantoprazole may increase toxicity of the antiretroviral drugs.
- **Warfarin:** Increased INR and prothrombin time in patients receiving PPIs, including pantoprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death.
- **Methotrexate:** Concomitant use of PPIs with methotrexate (primarily at high dose) may elevate and prolong serum concentrations of methotrexate and/or its metabolite hydroxymethotrexate, possibly leading to methotrexate toxicities. No formal drug interaction studies of high-dose methotrexate with PPIs have been conducted.
- **Drugs Dependent on Gastric pH for Absorption (e.g., iron salts, erlotinib, dasatinib, nilotinib, mycophenolate mofetil, ketoconazole/itraconazole):** Pantoprazole can reduce the absorption of other drugs due to its effect on reducing intragastric acidity.
- **Interactions with Investigations of Neuroendocrine Tumors:** CgA levels increase secondary to PPI-induced decreases in gastric acidity. The increased

CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors.

- ***False Positive Urine Tests for THC:*** There have been reports of false positive urine screening tests for tetrahydrocannabinol (THC) in patients receiving PPIs.

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm.

Please see full Prescribing Information for additional safety information.

Disclaimer: This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as “potential,” “can,” “will,” “plan,” “expect,” “anticipate,” “look forward,” “believe,” “committed,” “investigational,” “pipeline,” “launch,” “to provide,” “to deliver,” “to ensure,” or similar terms, or by express or implied discussions regarding potential future revenues from the products described in this press release, or discussions regarding the manufacture and supply of critical injectable generic products to help reduce supply shortages in acute care settings. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that the products described in this press release will be commercially successful in the future. Nor can there be any guarantee that the activities and efforts described in this release, including the collaboration with Civica Rx, will achieve any or all of its intended goals, or succeed, in the expected time frame or at all. In particular, our expectations regarding such products and the collaboration with Civica Rx could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional generic or biosimilar versions of such products; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit Sandoz from selling its products; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking

statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars. Our purpose is to pioneer access for patients by developing and commercializing novel, affordable approaches that address unmet medical need. Our ambition is to be the world's leading and most valued generics company. Our broad portfolio of high-quality medicines, covering all major therapeutic areas, accounted for 2019 sales of USD 9.7 billion.

Sandoz on social media

LinkedIn: <https://www.linkedin.com/company/sandoz/>

Twitter: https://twitter.com/sandoz_global

Facebook: <https://www.facebook.com/sandozglobal/>

Instagram: <https://www.instagram.com/sandozglobal>

CEO Richard Saynor on LinkedIn: <https://www.linkedin.com/in/richard-saynor/>

References

1. Pantoprazole Sodium injection. Prescribing Information. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27c6ccc3-1041-402e-b3bc-fc779a27d584>. Accessed September 8, 2020.

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