New

NOW OTC FOR FREQUENT HEARTBURN

Nexium® 24HR

PHARMASSIST KIT



Tools and information for you and your pharmacy team

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Nexium® 24HR PHARMASSIST KIT

Dear Pharmacist,

New Nexium® 24HR (esomeprazole 20 mg) has been **approved for OTC** use for the treatment of frequent heartburn and has arrived in stores. Nexium 24HR is available in 20 mg capsules and contains the same active ingredient as prescription NEXIUM®*, the #1 prescribed acid blocker brand.[1] Nexium 24HR can help your patients with frequent heartburn get the acid control they need.

As a pharmacist, you play an important role in helping patients make informed decisions about treatments for frequent heartburn. This *Nexium 24HR PharmAssist Kit* from Pfizer Consumer Healthcare provides you with information and tools you can use to be better prepared for patient consultations about Nexium 24HR.

Enclosed, you'll find:

Pharmacy Information sheet that highlights why this new acid blocker may be an appropriate choice for your patients with frequent heartburn



Patient Discussion Guide that can help you answer patient questions about Nexium 24HR



FAQ sheet that provides answers to a number of questions you may have about Nexium 24HR



This is an exciting opportunity that will benefit both your customers and your pharmacy, and we are happy to support you with helpful information about Nexium 24HR. If you would like additional copies of this kit, informational brochures with or without coupons, or more information, contact us at **1-888-278-6528**. You can also download and print additional copies of the FAQ sheet at **HCP.Nexium24HR.com**.

Your partners at Pfizer Consumer Healthcare

*NEXIUM 20 mg and 40 mg will remain available by prescription. Nexium 24HR may take 1 to 4 days to reach its full effect.

Reference: 1. IMS Health. National Prescription Audit, 2013.

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New

Increased OTC acid suppression for patients with frequent heartburn[1,2*]

Nexium® 24HR is now OTC

Esomeprazole 20 mg, the active ingredient in Nexium 24HR, provides increased acid suppression over other OTC proton pump inhibitors (PPIs)[1,2*]

- This includes omeprazole 20 mg (equivalent to Prilosec OTC®[†]), which is a racemic mixture comprised of both the S-isomer and the R-isomer[1]
- Esomeprazole contains only the S-isomer, which is more bioavailable than the R-isomer[1]

Increased acid suppression for a longer duration than omeprazole 20 mg[1*]

↑80% more acid blockers delivered to the source than omeprazole 20 mg[1‡]

+ 2hr at gastric pH >4 than omeprazole 20 mg[1*§]



*Acid control (pH >4) does not imply symptom relief. The correlation of pH data to clinical outcome has not been directly established.

[†]Prilosec OTC contains the active ingredient omeprazole magnesium 20.6 mg, equivalent to omeprazole 20 mg, used in this study.

[‡]Based on a pharmacokinetic study. The correlation of pharmacokinetic variables to clinical outcome has not been directly established.

[§]Mean value among 36 patients.

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Which patients should consider Nexium 24HR for frequent heartburn?

Patients who are:

- New to OTCs for frequent heartburn (heartburn occurring 2 or more times a week)
- Not getting adequate relief with antacids or H_2 blocker medications
- OTC PPI users who are dissatisfied with their current treatment

Rx patients who:

- Want easier access with an OTC for frequent heartburn
- Can't afford the copay of their Rx PPI
- Have had a change in formulary coverage and whose PPI is no longer covered

Recommend Nexium 24HR for your patients with frequent heartburn



References: 1. Lind T, Rydberg L, Kylebäck A, et al. Esomeprazole provides improved acid control vs. omeprazole in patients with symptoms of gastro-oesophageal reflux disease. *Aliment Pharmacol Ther.* 2000;14:861-867. **2.** Wilder-Smith C, Lind T, Lundin C, et al. Acid control with esomeprazole and lansoprazole: a comparative dose-response study. *Scand J Gastroenterol*. 2007;42(2):157-164.

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Insights for discussions with patients about **Nexium® 24HR**

Q: I'm getting heartburn a couple of times a week. Which medication would you recommend?

A: If you have heartburn 2 or more times a week, that's considered frequent heartburn.[1] There are medications called proton pump inhibitors, or PPIs, that are indicated specifically for people with frequent heartburn. One over-the-counter PPI you might want to consider is Nexium 24HR. It's the #1 prescribed acid blocker brand,[2] and it just became available without a prescription for frequent heartburn.

INSIGHT: *Once the patient confirms he/she is experiencing heartburn 2 or more times a week, consider recommending an OTC PPI such as Nexium 24HR, which is indicated for frequent heartburn.[1] Also, evaluate when it may be appropriate for the patient to speak with his/her physician.*

Q: Is Nexium 24HR for everyone?

A: No. Nexium 24HR is for adults 18 years and older who have frequent heartburn, which is 2 or more times a week. Nexium 24HR is not for patients under 18 or those who have 1 episode of heartburn a week or less, or who want immediate relief of heartburn.[1]

INSIGHT: *It's important that patients understand that Nexium 24HR is indicated only for patients with frequent heartburn, aged 18 years or older.[1] Those who ask about children under 18 years of age taking it should be referred to their doctor.*

Q: How is Nexium 24HR different from the other heartburn medications I see on the shelves?

A: Nexium 24HR and other PPIs are the only medications that are specifically for frequent heartburn. They work differently than other OTC medications for heartburn, such as antacids or histamine$_2$ blockers:

- PPIs stop acid production at the source by blocking the pumps that release acid into the stomach.[3]
- Antacids relieve heartburn by neutralizing existing stomach acid, but you have to take them several times a day.[4]
- Histamine$_2$ blockers block just 1 signal that tells the stomach to produce acid, and while they work longer than antacids, they don't provide relief for as long as a PPI like Nexium 24HR.[4]

INSIGHT: *Patients looking for an OTC to treat their frequent heartburn should gain an understanding of the differences between PPIs, antacids, and histamine$_2$ blockers so they can make an educated decision about their OTC treatment options.*



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Q: How quickly does Nexium 24HR work?

A: Because the acid-releasing proton pumps in the stomach are not all active at the same time, it may take 1 to 4 days for a PPI—such as Nexium 24HR—to build up and work on enough active pumps to reach full effect.[5-8]

INSIGHT: *Understanding that PPIs like Nexium 24HR can take up to 4 days to reach full effect may help allay patient fears that the medication is not working properly.*

Q: My doctor prescribed NEXIUM® for me in the past. How is Nexium 24HR different?

A: Nexium 24HR is indicated for the treatment of frequent heartburn.[1] The active ingredient in Nexium 24HR is the same as in prescription NEXIUM,[1] but there are differences in indications and directions for use. Prescription NEXIUM is still available, but it is indicated for many acid-related conditions.[3]

INSIGHT: *Sharing this information will help patients who have been previously prescribed NEXIUM to understand that they now have an OTC option—one that is indicated specifically for treating their frequent heartburn.*[1]

Q: My health insurer just informed me they won't allow my doctor to prescribe my medication for frequent heartburn anymore. Can you recommend something else?

A: If you have heartburn 2 or more times a week, you should consider an over-the-counter PPI, which is specifically indicated for frequent heartburn. One PPI you might want to try is Nexium 24HR, which is now available without a prescription for frequent heartburn. Nexium 24HR has the same active ingredient as prescription NEXIUM, the #1 prescribed acid blocker brand.[2]

INSIGHT: *Nexium 24HR has the same active ingredient as prescription NEXIUM to treat frequent heartburn. Prescription NEXIUM 20 mg and 40 mg will still remain available.*

Q: I see that Nexium 24HR comes in 3 different packages. Is one stronger than the others?

A: No. All 3 packages offer the same strength of Nexium 24HR. The smallest box offers 1 course of treatment for frequent heartburn, which is 14 days. The other boxes offer more courses of treatment. But you should not take Nexium 24HR for more than 14 days, or more than 1 course of treatment every 4 months, unless directed by a doctor.[1]

INSIGHT: *With up to 3 courses of treatment in 1 package, Nexium 24HR makes treating heartburn very convenient for your patients.*

Your patients may have other questions about Nexium 24HR or the treatment of frequent heartburn. They can access a full list of frequently asked questions, safety information, and other product-specific answers at **Nexium24HR.com**.

References: 1. Nexium 24HR Drug Facts, Pfizer Inc, 2014. **2.** IMS Health. National Prescription Audit; 2013. **3.** NEXIUM [package insert]. Wilmington, DE: AstraZeneca LP; 2014. **4.** Zweber A, Berardi RR. Heartburn and dyspepsia. In: Berardi RR, ed. *The Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care*. 17th ed. Washington, DC: American Pharmacists Association; 2012:219-235. **5.** Shin JM, Vagin O, Munson K, et al. Molecular mechanisms in therapy of acid-related diseases. *Cell Mol Life Sci.* 2008;65(2):264-281. **6.** Sachs G, Shin JM, Howden CW. Review article: the clinical pharmacology of proton pump inhibitors. *Aliment Pharmacol Ther*. 2006;23(suppl 2):2-8. **7.** Shin JM, Munson K, Vagin O, Sachs G. The gastric HK-ATPase: structure, function, and inhibition. *Pflugers Arch*. 2009;457(3):609-622. **8.** Wolfe MM, Sachs G. Acid suppression: optimizing therapy for gastroduodenal ulcer healing, gastroesophageal reflux disease, and stress-related erosive syndrome. *Gastroenterology.* 2000;118(2 suppl 1):S9-S31.

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FAQs About Nexium® 24HR

Q: What is the indication for Nexium 24HR and how does it differ from the indications for the prescription formulation?

A: Nexium 24HR (esomeprazole 20 mg capsules) is indicated for the treatment of frequent heartburn (2 or more days a week) in adults 18 years of age or older. Nexium 24HR capsules are indicated for 14-day treatment of frequent heartburn.[1]

NEXIUM® (esomeprazole) is still available by prescription (20 mg and 40 mg) and is indicated for the treatment of gastroesophageal reflux disease (GERD), risk reduction of NSAID-associated gastric ulcer, *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence, and pathological hypersecretory conditions, including Zollinger-Ellison syndrome.[2]

Q: Will NEXIUM continue to be available as a prescription now that Nexium 24HR is available OTC?

A: Yes, NEXIUM will continue to be available as a prescription medication for its currently

Q: How is Nexium 24HR sold in stores?

A: Nexium 24HR is available in 14-capsule, 28-capsule, and 42-capsule sizes. These sizes contain 1, 2, and 3 courses of 14-day treatment, respectively. Nexium 24HR should not be used for more than 14 days in a row unless directed by a doctor. With the 28 count (two 14-day courses) and the 42 count (three 14-day courses), patients may repeat a 14-day course every 4 months.



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Q: Who should take Nexium 24HR?

A: Adults who are 18 years of age or older with frequent heartburn (2 or more days per week) can take Nexium 24HR.[1] It is important to read and carefully follow the labeling directions for use of Nexium 24HR. Those who should not take Nexium 24HR include[1]:

- Children under 18 years of age
- People who have 1 episode or less of heartburn per week
- Those who want immediate relief of heartburn
- People with known hypersensitivity to esomeprazole magnesium or any of the ingredients in Nexium 24HR
- People who have trouble or pain swallowing food, vomiting with blood, or bloody or black stools, as these may be signs of a serious condition

Q: How quickly will Nexium 24HR work?

A: Because the acid-releasing proton pumps in the stomach are not all active at the same time, it may take 1 to 4 days for a PPI—such as Nexium 24HR—to build up and work on enough active pumps to reach full effect.[3-6]

Q: What is the mechanism of action of Nexium 24HR?

A: Esomeprazole is a PPI that suppresses gastric acid secretion by specific inhibition of H^+/K^+ ATPase in the gastric parietal cell. The S-isomer of omeprazole is protonated and converted in the acidic compartment of the parietal cell forming the active inhibitor, the achiral sulphenamide. By acting specifically on the proton pump, esomeprazole blocks the final step in acid production, thus reducing gastric acidity.[2]

Q: How is Nexium 24HR different compared to Prilosec OTC®?

A: Nexium 24HR and Prilosec OTC are both over-the-counter PPIs, but they have different active ingredients. Omeprazole 20 mg (equivalent to Prilosec OTC*) is a racemic mixture, which is a compound composed of two isomers: the S- and R-isomers. Esomeprazole contains only the S-isomer, which is more bioavailable than the racemic mixture, and therefore delivers 80% more acid blockers to the source compared to omeprazole 20 mg (equivalent to Prilosec OTC*).[7†] By having only the S-isomer, esomeprazole—the active ingredient in Nexium 24HR—is more effective in suppressing acid.[7‡]

*Prilosec OTC contains the active ingredient omeprazole magnesium 20.6 mg, equivalent to omeprazole 20 mg, used in this study.

†Based on a pharmacokinetic study. The correlation of pharmacokinetic variables to clinical outcome has not been directly established.

‡Acid control (pH >4) does not imply symptom relief. The correlation of pH data to clinical outcome has not been directly established.

References: 1. Nexium 24HR Drug Facts, Pfizer Inc, 2014. **2.** NEXIUM [package insert]. Wilmington, DE: AstraZeneca LP; 2014. **3.** Shin JM, Vagin O, Munson K, et al. Molecular mechanisms in therapy of acid-related diseases. *Cell Mol Life Sci.* 2008;65(2):264-281. **4.** Sachs G, Shin JM, Howden CW. Review article: the clinical pharmacology of proton pump inhibitors. *Aliment Pharmacol Ther.* 2006;23(suppl 2):2-8. **5.** Shin JM, Munson K, Vagin O, Sachs G. The gastric HK-ATPase: structure, function, and inhibition. *Pflugers Arch.* 2009;457(3):609-622. **6.** Wolfe MM, Sachs G. Acid suppression: optimizing therapy for gastroduodenal ulcer healing, gastroesophageal reflux disease, and stress-related erosive syndrome. *Gastroenterology.*

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