

June 01, 2009



Thank you for your inquiry about Xanax™ (alprazolam). Pfizer Inc is pleased to provide you with the following information in response to your specific request. PLEASE NOTE that this information is intended only for the specific person who has requested information about a specific Pfizer Inc product. IF YOU DID NOT SPECIFICALLY REQUEST THE INFORMATION THAT IS INCLUDED, PLEASE DISCARD IT AND CALL 1-800-438-1985 TO REPORT THIS TO US. Your request concerned:

- gluten content of Greenstone prescription products
- gluten content of Pfizer prescription products

XANAX is indicated for the management of anxiety disorder (a condition corresponding most closely to generalized anxiety disorder) or the short-term relief of symptoms of anxiety.

XANAX is indicated for the treatment of panic disorder, with or without agoraphobia. Please refer to the package insert for complete prescribing information.

I hope this information is helpful. Thank you for your interest in Pfizer. Please contact Pfizer at 1-800-438-1985 to report an Adverse Event or if you have any other questions regarding Pfizer products. Licensed healthcare professionals may also log on to www.pfizermedicalinformation.com. Please take a few moments to let us know how we are meeting your needs by completing our survey via the web at <http://survey.pfizermedicalinformation.com> using the reference number listed below the signature at the end of this letter.

Sincerely,

A handwritten signature in black ink that reads "Joanne Gibson RN". The signature is written in a cursive style with a large initial "J" and "G".

Joanne Gibson, RN
Medical Customer Interface Manager
Pfizer U.S. Medical Information

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Encl.

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gluten content of Greenstone prescription products

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Greenstone Limited is a subsidiary of Pfizer Inc. Please note that Greenstone Limited lists active and most inactive ingredients in the package inserts or on the product containers. Inactive ingredients present in trace amounts (e.g., imprint ink) may not be listed. The accuracy of our statements is based upon the final product composition formula only and cannot guarantee that minute amounts of substances are not contained in raw materials obtained from various suppliers for our manufacturing process.

Gluten is a mixture of two proteins, gliadin and glutenin, that are present in wheat flour and to a lesser extent in barley, oats, and rye.¹

The Greenstone Limited products in Table 1 below contain gluten as an ingredient. Please note that Table 1 does not contain a complete listing of all Greenstone Limited pharmaceutical products.

Table 1. Greenstone Limited Products That DO Contain Gluten²

Colestipol HCl Flavored Granules for Oral Suspension *
* Please note that Colestipol HCl Flavored Granules for Oral Suspension DO contain gluten, and that Colestipol HCl Tablets and Granules for Oral Suspension DO NOT contain gluten.

The Greenstone Limited products in Table 2 below do not contain gluten as an ingredient. Please note that Table 2 does not contain a complete listing of all Greenstone Limited pharmaceutical products.

Table 2. Greenstone Limited Products That DO NOT Contain Gluten²

Alprazolam Tablets
Alprazolam XR [extended release] Tablets
Amlodipine Besylate Tablets
Azithromycin Oral Suspension, Single-Dose Powder Packets, Tablets (all strengths of formulations)
Cabergoline Tablets
Clindamycin Hydrochloride Capsules
Colestipol HCl Tablets, Granules for Oral Suspension *
Eplerenone Tablets
Fluconazole Oral Suspension, Tablets
Gabapentin Capsules, Tablets
Glipizide XL [extended release] Tablets
Glyburide Tablets
Methylprednisolone Tablets
Quinapril HCl Tablets
Sertraline HCl Oral Concentrate, Tablets
Spironolactone Tablets
Spironolactone/hydrochlorothiazide Tablets
Sulfasalazine Tablets
Sulfasalazine [delayed release] Tablets
Triazolam Tablets
* Please note that Colestipol HCl Flavored Granules for Oral Suspension DO contain gluten, and that Colestipol HCl Tablets and Granules for Oral Suspension DO NOT contain gluten.

Refs.

1. Sweetman SC. *Martindale: The Complete Drug Reference*. 33rd ed. London, UK: Pharmaceutical Press, 2002.
2. Data on file (53) – Pfizer Inc. Database search on March 17, 2009.

Please note that Pfizer Inc lists active and most inactive ingredients in the package inserts or on the product containers. Inactive ingredients present in trace amounts (e.g., imprint ink) may not be listed. **The accuracy of our statements is based upon the final product composition formula only and cannot guarantee that minute amounts of substances are not contained in raw materials obtained from various suppliers for our manufacturing process.**

Gluten is a mixture of two proteins, gliadin and glutenin, that are present in wheat flour and to a lesser extent in barley, oats, and rye.¹

The Pfizer U.S. pharmaceutical products in Table 1 below do contain gluten as an ingredient. Please note that Table 1 does not contain a complete listing of all Pfizer pharmaceutical products.

Table 1. Pfizer U.S. Pharmaceutical Products That DO Contain Gluten as an Ingredient²

Aromasin® (exemestane) Tablets
Colestid® (colestipol HCl) Flavored Granules for Oral Suspension *
Exubera® (insulin human [rDNA origin]) Inhalation Powder
Nardil® (phenelzine sulfate) Tablets
Neurontin® (gabapentin) Oral Solution †
Sutent® (sunitinib malate) Capsules
Toviaz™ (fesoterodine fumarate, extended-release) Tablets
Zyvox® (linezolid) for Oral Suspension ‡
* Please note that Colestid® (colestipol HCl) Flavored Granules for Oral Suspension DO contain gluten; and that Colestid® (colestipol HCl) Tablets and Granules for Oral Suspension DO NOT contain gluten. † Please note that Neurontin® (gabapentin) Oral Solution DOES contain gluten, and that Neurontin® (gabapentin) Capsules and Tablets DO NOT contain gluten. ‡ Please note that Zyvox® (linezolid) for Oral Suspension DOES contain gluten, and that Zyvox® (linezolid) Tablets DO NOT contain gluten.

The Pfizer U.S. pharmaceutical products in Table 2 below do not contain gluten as an ingredient. Please note that Table 2 does not contain a complete listing of all Pfizer pharmaceutical products.

Table 2. Pfizer U.S. Pharmaceutical Products That DO NOT Contain Gluten as an Ingredient²

Accupril® (quinapril HCl) Tablets
Aldactazide® (spironolactone/hydrochlorothiazide) Tablets
Aldactone® (spironolactone) Tablets
Aricept® (donepezil HCl) Tablets
Aricept® ODT (donepezil HCl, orally disintegrating) Tablets ³

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Arthrotec® (diclofenac sodium/misoprostol) Tablets
Azulfidine® (sulfasalazine) Tablets
Azulfidine EN-tabs® (sulfasalazine, delayed release) Tablets
Caduet® (amlodipine besylate/atorvastatin calcium) Tablets
Cardura®XL (doxazosin mesylate, extended release) Tablets
Celebrex® (celecoxib) Capsules
Chantix™ (varenicline) Tablets
Cleocin® (clindamycin hydrochloride) Capsules
Cleocin® (clindamycin) Pediatric Flavored Granules for Oral Solution
Colestid® (colestipol HCl) Tablets, Granules for Oral Suspension *
Cortef® (hydrocortisone) Tablets
Detrol® (tolterodine) Tablets
Detrol®LA (tolterodine, extended release) Capsules
Diflucan® (fluconazole) Tablets, Oral Suspension
Dilantin® (phenytoin) Capsules, Infatabs, Kapseals, Oral Suspension § £
Dostinex® (cabergoline) Tablets
Estring® (estradiol) Vaginal Ring
Geodon® (ziprasidone HCl) Capsules
Glucotrol® (glipizide) Tablets
Glucotrol XL® (glipizide, extended release) Tablets
Glyset® (miglitol) Tablets
Halcion® (triazolam) Tablets
Inspra® (eplerenone) Tablets
Lipitor® (atorvastatin calcium) Tablets
Lomotil® (diphenoxylate hydrochloride/atropine sulfate) Tablets, Liquid
Lyrica® (pregabalin) Capsules
Medrol® (methylprednisolone) Tablets
Micronase® (glyburide) Tablets
Neurontin® (gabapentin) Capsules, Tablets †
Norvasc® (amlodipine besylate) Tablets
Relpax® (eletriptan hydrobromide) Tablets
Revatio™ (sildenafil citrate) Tablets
Selzentry™ (maraviroc) Tablets
Tikosyn® (dofetilide) Capsules

Vantin® (cefpodoxime proxetil) Tablets, Oral Suspension
Vfend® (voriconazole) Tablets, Oral Suspension
Viagra® (sildenafil citrate) Tablets
Vibramycin® (doxycycline calcium) Oral Syrup
Vibramycin® (doxycycline hyclate) Capsules
Vibramycin® (doxycycline monohydrate) Oral Suspension
Vibra-Tabs® (doxycycline hyclate) Film Coated Tablets
Xanax® (alprazolam) Tablets
Xanax XR® (alprazolam, extended release) Tablets
Zithromax® (azithromycin) Tablets, Oral Suspension, Single-Dose Powder Packets (1g)
Zmax™ (azithromycin, extended release) Oral Suspension
Zoloft® (sertraline HCl) Tablets, Oral Concentrate
Zyvox® (linezolid) Tablets ‡
<p>* Please note that Colestid® (colestipol HCl) Flavored Granules for Oral Suspension DO contain gluten; and that Colestid® (colestipol HCl) Tablets and Granules for Oral Suspension DO NOT contain gluten.</p> <p>† Please note that Neurontin® (gabapentin) Oral Solution DOES contain gluten, and that Neurontin® (gabapentin) Capsules and Tablets DO NOT contain gluten.</p> <p>‡ Please note that Zyvox® (linezolid) for Oral Suspension DOES contain gluten, and that Zyvox® (linezolid) Tablets DO NOT contain gluten.</p> <p>§ Pfizer discontinued the manufacturing of Dilantin Kapseals 100 mg in September 2007, but they may remain in distribution until the supply is exhausted. The Dilantin Kapseals 30 mg strength is still available.</p> <p>£ Dilantin 100 mg Capsules are produced using updated manufacturing methods; and the National Drug Code (NDC) numbers have been changed from the discontinued 100 mg Kapseals NDCs of 0071-0362-24; 0071-0362-32; and 0071-0362-40 to the new 100 mg Capsule formulation NDCs 0071-0369-24; 0071-0369-32; and 0071-0369-40.</p>

Refs.

1. Sweetman SC. *Martindale: The Complete Drug Reference*. 33rd ed. London, UK: Pharmaceutical Press, 2002.
2. Data on file (53) – Pfizer Inc. Database search on April 21, 2009.
3. Data on file (57) – Pfizer Inc.