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Bridging Science, Policy and Public Health

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September 22, 2015

Captain Krista Pedley
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

Dear Captain Pedley:

The National Alliance of State and Territorial AIDS Directors (NASTAD) has been actively monitoring recent price increases for Daraprim (pyrimethamine), an antiparasitic agent used to treat toxoplasmosis in patients with HIV, including AIDS Drug Assistance Program (ADAP) clients. Following a recent transfer of ownership to Turing Pharmaceuticals, several ADAPs have experienced difficulty in acquiring Daraprim at the 340B price.

NASTAD is concerned that Turing's distribution arrangements are in violation of the 340B Drug Discount Program's non-discrimination provisions. NASTAD understands that, for outpatient prescriptions, Turing has a sole distribution agreement with Walgreens Specialty Pharmacy. However, it appears that Turing has not made the 340B price available to eligible 340B covered entities through Walgreens, instead only allowing purchases at the 340B price through a separate, drop-ship mechanism available through ICS Connect.

On September 22, 2015, Turing's website for Daraprim, DaraprimDirect.com, directed prescribers to order through Walgreens Specialty Pharmacy; the website contains a separate drop-down box titled "For Hospital Pharmacists (Including: Institutions and 340B Facilities)" that provides separate ordering information through ICS Connect for 340B pricing. Previously, Turing's website made the separate distribution channels more explicit, as seen in the attached website capture. On September 12, 2015, Turing's website labeled the distribution channels as "Walgreens Specialty Pharmacy" for all "Outpatient/Retail" orders and "Integrated Commercial Services (ICS)" for all "Inpatient Pharmacies, Government Customers, and 340B/PHS Customers."

The Health Resources and Services Administration's (HRSA) regulations prohibit manufacturers from "singl[ing] out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" of the 340B program and from "plac[ing] limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." (59 Fed. Reg. 25110 (May 13, 1994)) This prohibition, known as the non-discrimination provision, requires manufacturers to make 340B prices available to covered entities through the same distribution channels available to other purchasers. Without this protection, manufacturers could attempt to limit participation in the 340B program by placing additional barriers in the way of covered entities, ultimately harming patients.

Indeed, Turing's restrictive purchasing program for 340B covered entities has harmed patients. Georgia has removed Daraprim from its ADAP formulary because it was unable to purchase Daraprim at the 340B price. Georgia, like many states, is only able to purchase drugs through vendors that have gone through state approval processes and is unable to make one-off drug

purchases through ICS Connect. Because the 340B price was not available through Walgreens Specialty Pharmacy and thus not available through any of the Georgia ADAP's standard purchasing channels, Georgia was forced to remove Daraprim from the formulary because of the excessive price. ADAP clients in Georgia who need Daraprim must access it through charity care or a patient assistance program, which can lead to delays in care that impact patient health. NASTAD is aware of ADAPs that have been able to establish accounts with ICS Connect after receiving special approval from their state purchasing authorities; however, this extra administrative process to receive 340B pricing is precisely the type of discriminatory barrier prohibited in the 340B program.

It is apparent that Turing has violated HRSA's non-discrimination requirements for the 340B program, and NASTAD believes that this discriminatory restriction on purchasing at the 340B price is ongoing. NASTAD requests that HRSA investigate Turing's violations of the non-discrimination requirement and imposes appropriate penalties.

We appreciate your investigation of this matter. Please contact me if you have questions or need additional information.

Sincerely,



Murray C. Penner
Executive Director, NASTAD

CC: Sen. Bernie Sanders, U.S. Senate
Rep. Elijah Cummings, U.S. House of Representatives
Michelle Herzog, Deputy Director, Office of Pharmacy Affairs
Heather Hauck, Director, Division of State HIV/AIDS Programs
Michael Goldrosen, Deputy Director, Division of State HIV/AIDS Programs
Glenn Clark, ADAP Advisor, Division of State HIV/AIDS Programs
Ann Lefert, Senior Director, Prevention/Care Program and Policy, NASTAD
Sean Dickson, Manager, Health Care Access, NASTAD

Attachment (1)

You have reached the cached page for <http://www.daraprimdirect.com/how-to-prescribe>
(<http://www.daraprimdirect.com/how-to-prescribe>)

Below is a snapshot of the Web page as it appeared on **9/12/2015** (the last time our crawler visited it). This is the version of the page that was used for ranking your search results. The page may have changed since we last cached it. To see what might have changed (without the highlights), go to the current page (<http://www.daraprimdirect.com/how-to-prescribe>).

You searched for: **daraprimdirect 340b** We have highlighted matching words that appear in the page below.

Bing is not responsible for the content of this page.

How to Prescribe

**Now available exclusively
through Walgreen's Specialty
Pharmacy**

[Click here to download Prescription and Enrollment form !\[\]\(3e2231b1ad3ca8da8658228c00dd08e0_img.jpg\)](#)

(</forms/Daraprim-Prescription-Form.pdf>)

Outpatient/Retail

Phone Walgreens Specialty Pharmacy

Walgreens Specialty Pharmacy can be promptly reached by dialing
1-844-463-2727

Download Prescription and Enrollment Form

Download Prescription and Enrollment Form by clicking here (</Daraprim-Prescription-Form.pdf>), have your physician complete and fax to
1-844-325-653

Inpatient/Pharmacy

Inpatient Pharmacies, Government Customers, and 340B/PHS Customers

Order through Integrated Commercial Services Inc (ICS) by calling ICS at 800-554-6919. ICS can also be contacted by email
daraprimdirectCS@icsconnect.com
(<mailto:daraprimdirectCS@icsconnect.com>)

[Prescribing Information](#)

[Privacy Policy](#)

[Turing Pharmaceuticals](#)

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Important Safety Information

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INDICATIONS

DARAPRIM (pyrimethamine) is indicated for the:

- Treatment of toxoplasmosis when used conjointly with a sulfonamide.
- Treatment of acute malaria only in patients infected in areas where susceptible plasmodia exist and when used conjointly with a sulfonamide (e.g., sulfadoxine) to initiate transmission control and suppression of susceptible strains of plasmodia. It should NOT be used alone to treat acute malaria. Fast-acting schizonticides such as chloroquine or quinine are indicated and preferable for the treatment of acute malaria.
- Chemoprophylaxis of malaria due to susceptible strains of plasmodia. It is not suitable as a prophylactic agent for travelers to most areas since resistance to pyrimethamine is prevalent worldwide.

IMPORTANT SAFETY INFORMATION

- DARAPRIM is **contraindicated** in patients with known hypersensitivity to pyrimethamine or to any component of the formulation and in patients with documented megaloblastic anemia due to folate deficiency.
- Potential for **folate deficiency**: Dosage required for toxoplasmosis treatment approaches the toxic level. If signs of folate deficiency develop, reduce the dosage or discontinue the drug according to patient response. Administer folinic acid (leucovorin) at 5-15 mg per day until normal hematopoiesis is restored.
- **Carcinogenic potential**: Data indicates that pyrimethamine may be carcinogenic.

Adverse reactions:

- **Hypersensitivity reactions**, occasionally severe (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, and anaphylaxis), **and hyperphenylalaninemia**, can occur particularly when pyrimethamine is administered concomitantly with a sulfonamide. Consult the full prescribing information for relevant sulfonamide-associated adverse events.
- **Megaloblastic anemia, leukopenia, thrombocytopenia, pancytopenia, atrophic glossitis, hematuria, cardiac rhythm disorders, anorexia and vomiting** may occur with doses used for toxoplasmosis treatment. Hematologic effects may also occur at low doses in certain individuals.
- **Pulmonary eosinophilia** has been reported rarely.

Pregnancy Category C:

- There are no adequate and well-controlled studies in pregnant women. DARAPRIM should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Women of childbearing potential should be warned against becoming pregnant during treatment with Daraprim.
- Pyrimethamine is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from pyrimethamine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- **Keep out of the reach of infants and children**: Deaths in pediatric patients have been reported after accidental ingestion.

Drug Interactions:

- The concomitant use of pyrimethamine with other antifolate drugs or agents associated with myelosuppression including sulfonamides or trimethoprim-sulfamethoxazole combination, proguanil, zidovudine, or cytostatic agents (e.g., methotrexate), may increase the risk of bone marrow suppression. If signs of folate deficiency develop, pyrimethamine should be discontinued and folinic acid should be given until hematopoiesis is restored (see above).
- Use Daraprim with caution in patients receiving therapy, such as phenytoin, that affect folate levels.
- Mild hepatotoxicity can occur when lorazepam and pyrimethamine are administered concomitantly.

Dosing Information:

- For specific dosing instructions see the Full Prescribing Information.
- Do not exceed the recommended dosage.
- Start with a small dose for toxoplasmosis in patients with convulsive disorders to avoid the potential nervous system toxicity of pyrimethamine (see Overdosage).
- Use with caution in patients with impaired renal or hepatic function; in patients with possible folate deficiency such as individuals with malabsorption syndrome, alcoholism, or who are pregnant; and in the elderly due to the potential for decreased hepatic, renal, or cardiac function, and concomitant disease or other drug therapy in this population.
- Concurrent administration of folinic acid is strongly recommended when used for the treatment of toxoplasmosis in **ALL** patients.
- In patients receiving a high dosage, as for the treatment of toxoplasmosis, semiweekly blood counts, including platelet counts should be performed.
- Taking Daraprim with meals may minimize associated anorexia and vomiting.

Overdosage

- Following the ingestion of 300 mg or more of pyrimethamine, gastrointestinal and/or central nervous system signs may be present, including convulsions and death.
- There is no specific antidote to acute pyrimethamine poisoning. Symptomatic and supportive measures should be employed. Gastric lavage is recommended and is effective if carried out very soon after drug ingestion. Parenteral diazepam may be used to control convulsions. Folinic acid should be administered within 2 hours of drug ingestion to be most effective in counteracting the effects on the hematopoietic system. Daily monitoring of peripheral blood counts is recommended for up to several weeks until normal hematologic values are restored.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch (<http://www.fda.gov/medwatch>) or call 1-800-FDA-1088. To report SUSPECTED ADVERSE REACTIONS contact Turing Pharmaceuticals AG 1-877-258-2033 .

Please See Full Prescribing Information

DARAPRIM is a licensed trademark of Turing Pharmaceuticals AG.