

COMPANY ANNOUNCEMENT

Darmerica LLC Issues Voluntary Nationwide Recall of Quinacrine Dihydrochloride Due to A Labeling Error

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

September 12, 2019

FDA Publish Date:

September 12, 2019

Product Type:

Drugs

Reason for Announcement:

Label mix-up

Company Name:

Darmerica LLC

Brand Name:

Darmerica LLC

Product Description:

Quinacrine Dihydrochloride, bulk API powder

Company Announcement

Darmerica LLC is voluntarily recalling two lots, DR4654A and DL4654A, of Quinacrine Dihydrochloride, bulk API powder packaged in Amber HDPE Bottles to the consumer level. This product is being recalled due to a label mix-up. Product intended for further compounding use by pharmacies labeled as Quinacrine API was tested and identified as Artemisinin API. Artemisinin and its semisynthetic derivatives are a group of drugs used against malaria.

Receiving artemisinin rather than quinacrine could lead to deterioration of disease that is being treated, serious adverse reactions, due to prolonged exposure to artemisinin, which would need medical or surgical intervention as well as mistaken evaluation and remediation of adverse reactions. To date, Darmerica LLC has not received any reports of adverse events related to this recall.

The product is used as an antiprotozoal, antirheumatic, intrapleural sclerosing agent and was packaged in Amber HDPE bottles. The affected Quinacrine Dihydrochloride lots include the following lot numbers, DR4654A and DL4654A, and expiration date of April 27, 2021. The product can be identified by the label, as illustrated below. Quinacrine Dihydrochloride was distributed Nationwide to 14 Compounding Pharmacies.

Darmerica LLC is notifying its distributors and customers by e-mail and telephone and is arranging for return of all recalled products. Compounding Pharmacies that have Quinacrine Dihydrochloride which is being recalled should stop compounding and return it to Darmerica LLC. Compounding Pharmacies should probably initiate their own recalls if they manufactured/distributed product using these two lots.

Compounding Pharmacies with questions regarding this recall can contact Darmerica LLC by telephone at 407-766-9092 or Quality@darmerica.com (mailto:Quality@darmerica.com) (Monday to Friday, 9am to 5pm), Eastern Standard Time. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/forms-reporting-fda>) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Company Contact Information

Consumers:

Kyle Hamza

📞 407-766-9092

✉ Quality@darmerica.com (mailto:Quality@darmerica.com)

Product Photos



Quinacrine Dihydrochloride (98.25%)

Darmerica LLC
198 Wilshire Blvd
Casselberry, FL 32707
321-219-9111

Lot No. : DL4654A
CAS# : 69-05-6
NDC# : 71052-530-05

Mfg. Date : Apr 28, 2019
Exp. Date : Apr 27, 2021
Qty : 500 g

Handling: See Safety Data sheet.

Storage: Store in a sealed light-resistant container at room temperature.

Caution: For use and distribution in prescription compounding, manufacturing, processing or repacking only in accordance to FDA regulations and applicable law.
Relabeled by Darmerica



Quinacrine Dihydrochloride (98.25%)

Darmerica LLC
198 Wilshire Blvd
Casselberry, FL 32707
321-219-9111

Lot No. : DR4654A
CAS# : 69-05-6
NDC# : 71052-530-55

Mfg. Date : Apr 28, 2019
Exp. Date : Apr 27, 2021
Qty : 50 g

Handling: See Safety Data sheet.

Storage: Store in a sealed light-resistant container at room temperature.

Caution: For use and distribution in prescription compounding, manufacturing, processing or repacking only in accordance to FDA regulations and applicable law.
Repacked by Darmerica



Quinacrine Dihydrochloride (98.25%)

Darmerica LLC
198 Wilshire Blvd
Casselberry, FL 32707
321-219-9111


Lot No. : DR4654A
CAS# : 69-05-6
NDC# : 71052-530-25

Mfg. Date : Apr 28, 2019
Exp. Date : Apr 27, 2021
Qty : 25 g

Handling: See Safety Data sheet.

Storage: Store in a sealed light-resistant container at room temperature.

Caution: For use and distribution in prescription compounding, manufacturing, processing or repacking only in accordance to FDA regulations and applicable law.
Repacked by Darmerica

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