

Exceptional Importation of USA-Authorized Cholestyramine for Oral Suspension USP Sachets Due to the Current Shortage of Canadian-Authorized Cholestyramine for Oral Suspension

Juno Pharmaceuticals Corp.
402-2233 Argentia Road,
Mississauga, Ontario, Canada
L5N 2X7

April 15, 2024

Dear hospitals, wholesalers, pharmacists and healthcare professional associations:

There is a critical shortage of Cholestyramine for Oral Suspension (4 grams per sachet) in Canada.

In order to help mitigate the shortage, Health Canada has permitted the exceptional, temporary importation and sale of USA-authorized Cholestyramine for Oral Suspension, USP, with English only labels, by Juno Pharmaceuticals Corp., and has added this product to the List of Drugs for Exceptional Importation and Sale (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/list.html>).

In Canada, Cholestyramine for Oral Suspension (4 grams per sachet) is a prescription drug product indicated: as adjunctive therapy to diet and exercise for the reduction of elevated serum cholesterol in patients with primary hypercholesterolemia (elevated low-density lipoproteins); for lowering elevated cholesterol in patients with combined hypercholesterolemia and hypertriglyceridemia; as a symptomatic control of bile acid induced diarrhea due to short bowel syndrome; for the relief of pruritus associated with partial biliary obstruction.

The USA-authorized drug product is available in 9 gram of powder for oral suspension in single dose sachets and has the **same active ingredient (cholestyramine resin), strength (4 grams per sachet), dosage form (powder for suspension), and route of administration (oral)** as the Canadian-marketed products.

The USA-authorized drug product is a pale yellow to yellow coloured powder with an orange flavour. Pharmacists are advised to inform patients that the USA-authorized drug product may taste or appear different than the Canadian-marketed drug products due to differences in non-medicinal ingredients.

There are also differences in the approved indications; however, **the USA-authorized Cholestyramine for Oral Suspension USP can be used for the same indications as the Canadian-marketed Cholestyramine for Oral Suspension (4 grams per sachet) products.**

For proper use of the USA drug product, and for information on the indications, contraindications, warnings and precautions, adverse reactions, dosing and administration, and storage, healthcare professionals should refer to the Canadian Product Monograph for Olestyr (cholestyramine resin) available in English and French on the Health Canada Drug Product Database (<https://health-products.canada.ca/dpd-bdpp/info?lang=eng&code=19757>).

Information on the imported product

Brand name	Dosage form, strength and route of administration	Product packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada
Cholestyramine for Oral Suspension USP	Powder for suspension, 4 grams cholestyramine resin per sachet, oral	9 gram single dose sachets provided in cartons of 60	USA NDC 27241-134-21 (sachet) NDC 27241-134-36 (carton)	Ajanta Pharma USA Inc.	Juno Pharmaceuticals Corp., Canada

The USA-authorized drug product contains the following non-medicinal ingredients: citric acid monohydrate, colloidal silicon dioxide, propylene glycol alginate, sucrose, xanthan gum, orange flavour, D&C yellow No. 10 alum lake, FD&C yellow No. 6 alum lake.

Information about the USA-authorized Cholestyramine for Oral Suspension USP for healthcare professionals is available online in English at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a0b64dfe-49bc-45d7-9281-9e9d6e296c40>.

Images of the USA-authorized product can be found in the Appendix below. Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the USA-authorized drug product may differ from marketed Cholestyramine for Oral Suspension (4 grams per sachet) products in Canada. **Proper selection of the intended drug product must be verified to avoid confusion with other drug products and prevent medication errors.**

The USA-authorized product does not have a drug identification number (DIN) or a barcode that scans in medication management systems in Canada. A facility-generated sticker may be required to enable barcode scanning and allow the product being dispensed and administered to be properly identified.

Reporting adverse drug reactions

Adverse drug reactions associated with the use of USA-authorized Cholestyramine for Oral Suspension USP should be reported to Juno Pharmaceuticals Corp. by calling 1-855-819-0505 or 1-

866-663-1747, or to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

Questions or concerns

For questions or concerns about USA-authorized Cholestyramine for Oral Suspension USP, please contact Juno Pharmaceuticals Corp., 402-2233 Argentia Road, Mississauga, ON, L5N 2X7 at <https://www.junopharm.ca>, or 1-866-663-1747.

Appendix

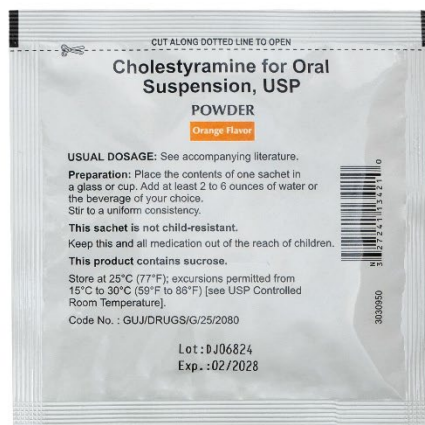
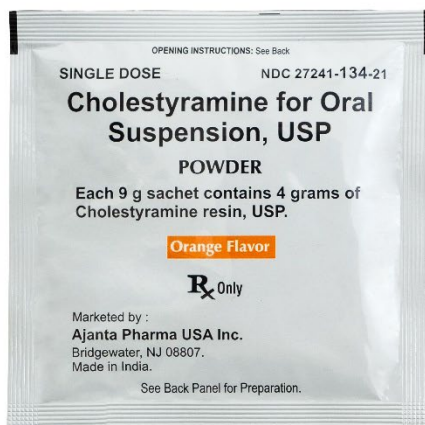
1. Images of USA-authorized Cholestyramine for Oral Suspension USP

Sincerely,

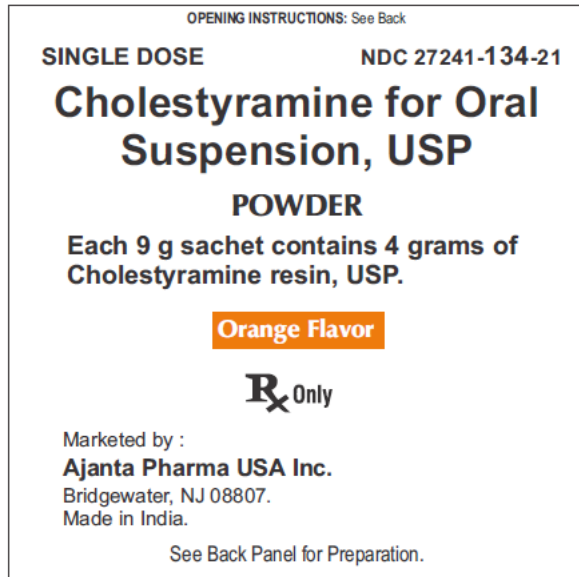
Paul J. Varady
VP, Quality and Regulatory Affairs
Juno Pharmaceuticals Canada

Appendix - Images of USA-Authorized Cholestyramine for Oral Suspension USP

USA Product Photos



USA Sachet Label - Front



Plain text USA Sachet Label - Front

Main Panel
Opening Instructions: See Back Single Dose NDC 27241-134-21 Cholestyramine for Oral Suspension, USP Powder Each 9 g sachet contains 4 grams of Cholestyramine resin, USP Orange Flavor Rx Only Marketed by: Ajanta Pharma USA Inc. Bridgewater, NJ 08807 Made in India. See Back Panel for Preparation


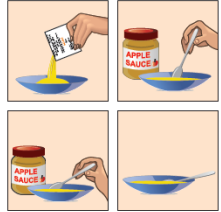
USA Sachet Label - Back



Plain text USA Sachet Label - Back

Main Panel
<p>Cut along dotted line to open</p> <p>Diagram of a dotted line with scissors indicating where to cut</p> <p>Cholestyramine for Oral Suspension, USP</p> <p>Powder</p> <p>Orange Flavor</p> <p>Usual Dosage: See accompanying literature.</p> <p>Preparation: Place the contents of one sachet in a glass or cup. Add at least 2 to 6 ounces of water or the beverage of your choice.</p> <p>Stir to a uniform consistency.</p> <p>This sachet is not child-resistant.</p> <p>Keep this and all medication out of the reach of children.</p> <p>This product contains sucrose.</p> <p>Store at 25°C (77°F), excursions permitted from 15°C to 30°C (59°F to 86°F) (see USP controlled room temperature)</p> <p>Code No. : GUJ/DRUGS/G/25/2080</p>

USA Carton Label – Main Panel and Side Panel

 <p style="text-align: right;">NDC 27241-134-36</p> <p style="text-align: center;">Cholestyramine for Oral Suspension, USP</p> <p style="text-align: center;">POWDER</p> <p>4 grams of Cholestyramine resin, USP, per sachet* *each 9 g sachet contains 4 grams of Cholestyramine resin, USP</p> <p>Rx Only</p> <p>60 Single Dose Sachets</p> <p>This product contains sucrose.</p> <p style="text-align: right;"><i>ajanta</i></p> <p style="text-align: center;">Orange Flavor</p>	<p>Preparation of Cholestyramine for Oral Suspension, USP</p> <p>Cholestyramine for Oral Suspension, USP can be easily mixed with highly fluid foods or fruits.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>1. Pour contents of one Cholestyramine for Oral Suspension, USP sachet in a bowl.</p> <p>2. Add at least 6 ounces of applesauce or other food.</p> </div> <div style="width: 45%;"> <p>3. Mix well.</p> <p>4. The slightly-textured Cholestyramine for Oral Suspension, USP mixture is now ready to eat.</p> </div> </div>  <p>NOTE: More than one sachet can be mixed at one time depending upon the amount of food you wish to consume when taking your Cholestyramine for Oral Suspension, USP. You may mix to suit your individual taste.</p>
---	--





Plain text USA Carton Label – Main Panel and Side Panel

<p>Main Panel</p> <p>Image of orange coloured mixed powder with sachet label behind it Orange Flavor NDC 27241-134-36 Cholestyramine for Oral Suspension, USP Powder 4 grams of Cholestyramine resin, USP, per sachet* *each 9 g sachet contains 4 grams of Cholestyramine resin, USP Rx Only 60 Single Dose Sachets This product contains sucrose ajanta logo</p>
<p>Side Panel</p> <p>Preparation of Cholestyramine for Oral Suspension, USP Cholestyramine for Oral Suspension, USP can be easily mixed with highly fluid foods or fruits. Diagram of 4 steps for mixing the drug product, one picture for each step.</p> <ol style="list-style-type: none"> 1. Pour contents of one Cholestyramine for Oral Suspension, USP sachet in a bowl. 2. Add at least 6 ounces of applesauce or other food. 3. Mix well. 4. The slightly-textured Cholestyramine for Oral Suspension, USP mixture is now ready to eat. <p>Note: More than one sachet can be mixed at one time depending upon the amount of food you wish to consume when taking your Cholestyramine for Oral Suspension, USP. You may mix to suit your individual taste.</p>


USA Carton Label – Alternate Side Panel

Preparation of Cholestyramine for Oral Suspension, USP Code No. : GUJ/DRUGS/G/25/2080

Cholestyramine for Oral Suspension, USP can be mixed with your choice of noncarbonated beverage.

1. Pour contents of one Cholestyramine for Oral Suspension, USP sachet into a glass or cup. 
2. Add 2 ounces of your favorite beverage (orange juice is a popular choice) and stir vigorously. 
3. Add at least 2 to 4 more ounces of beverage to suit individual taste and stir vigorously again. 
4. The slightly-textured Cholestyramine for Oral Suspension, USP mixture is now ready to drink. 

NOTE: More than one sachet can be mixed at one time depending upon the amount of beverage you wish to consume when taking your Cholestyramine for Oral Suspension, USP. You may mix to suit your individual taste.



USA Carton Label – Alternate Side Panel

Preparation of Cholestyramine for Oral Suspension, USP

Code No. : GUJ/DRUGS/G/25/2080

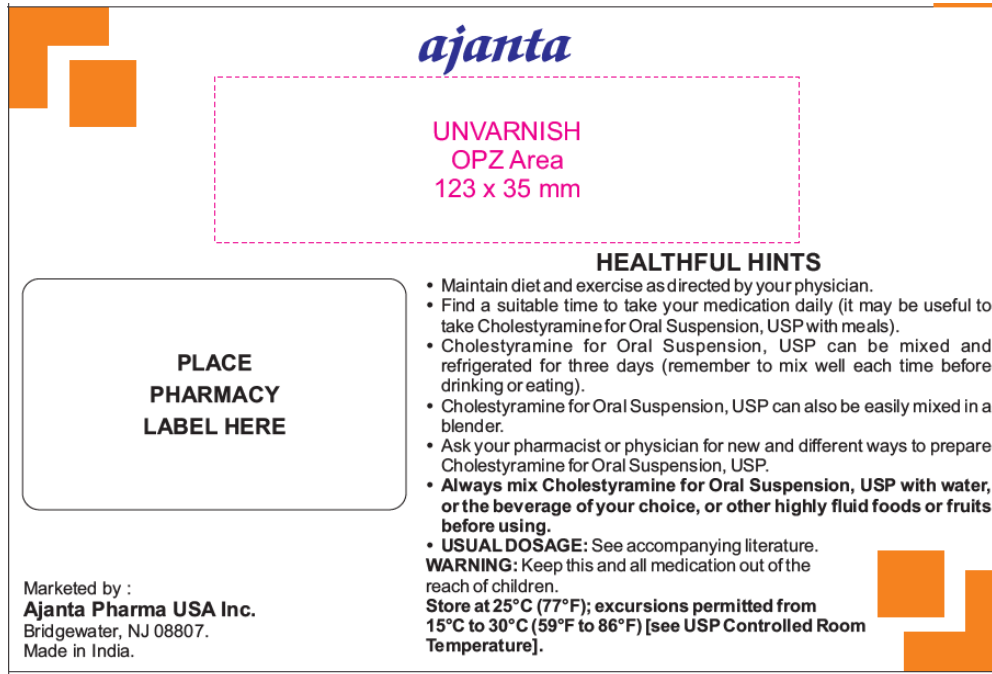
Cholestyramine for Oral Suspension, USP can be mixed with your choice of noncarbonated beverage.

Diagram of 4 steps for mixing the drug product, one picture for each step.

1. Pour contents of one Cholestyramine for Oral Suspension, USP sachet into a glass or cup.
2. Add 2 ounces of your favorite beverage (orange juice is a popular choice) and stir vigorously).
3. Add at least 2 to 4 more ounces of beverage to suit individual taste and stir vigorously again.
4. The slightly-textured Cholestyramine for Oral Suspension, USP mixture is now ready to drink.

Note: More than one sachet can be mixed at one time depending upon the amount of beverage you wish to consume when taking your Cholestyramine for Oral Suspension, USP. You may mix to suit your individual taste.

USA Carton Label – Top Panel



ajanta

UNVARNISH
OPZ Area
123 x 35 mm

PLACE
PHARMACY
LABEL HERE

HEALTHFUL HINTS

- Maintain diet and exercise as directed by your physician.
- Find a suitable time to take your medication daily (it may be useful to take Cholestyramine for Oral Suspension, USP with meals).
- Cholestyramine for Oral Suspension, USP can be mixed and refrigerated for three days (remember to mix well each time before drinking or eating).
- Cholestyramine for Oral Suspension, USP can also be easily mixed in a blender.
- Ask your pharmacist or physician for new and different ways to prepare Cholestyramine for Oral Suspension, USP.
- **Always mix Cholestyramine for Oral Suspension, USP with water, or the beverage of your choice, or other highly fluid foods or fruits before using.**
- **USUAL DOSAGE:** See accompanying literature.

WARNING: Keep this and all medication out of the reach of children.
Store at 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Marketed by :
Ajanta Pharma USA Inc.
Bridgewater, NJ 08807.
Made in India.

USA Carton Label - Top Panel

ajanta logo

Empty box with “Place Pharmacy Label Here”

Healthful Hints

Maintain diet and exercise as directed by your physician.

Find a suitable time to take your medication daily (it maybe useful to take Cholestyramine for Oral Suspension, USP with meals).

Cholestyramine for Oral Suspension, USP can be mixed and refrigerated for three days (remember to mix well each time before drinking or eating).

Cholestyramine for Oral Suspension, USP can also be easily mixed in a blender.

Ask your pharmacist or physician for new and different ways to prepare Cholestyramine for Oral Suspension, USP.

Always mix Cholestyramine for Oral Suspension, USP with water, or the beverage of your choice, or other highly fluid foods or fruits before using.

Usual dosage: See accompanying literature.

Warning: Keep this and all medication out of the reach of children.

Store at 25C (77f); excursions permitted from 15C to 30C (59F to 86F) [see USP Controlled Room Temperature].

Marketed by:

Ajanta Pharma USA Inc.

Bridgewater, NJ 08807

Made in India