

**Important Safety Information on COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine):  
New Formulation for Use in Children Aged 5 Years to Less Than 12 Years**



2021/11/19

**IMPORTANT: Access to Canadian-specific labelling information during the distribution of COMIRNATY (COVID-19 Vaccine, mRNA also referred to as Pfizer-BioNTech COVID-19 Vaccine) for Children Aged 5 Years to Less Than 12 Years.**

**Audience**

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners. Healthcare professionals at the identified Points of Use.

**Key messages**

- **On 19 November 2021, COMIRNATY (COVID-19 Vaccine, mRNA), DIN: 02522454, received a Notice of Compliance for a new formulation to be used in children 5 to less than 12 years of age.**
- **COMIRNATY is now indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.**
- **COMIRNATY is now authorized as two different formulations/presentations, which are clearly differentiated by their cap colour (see Appendix A and Appendix B):**
  - **PURPLE CAP (30 mcg/0.3 mL after dilution): for use in individuals 12 years of age and older;**
  - **ORANGE CAP (10 mcg/0.2 mL after dilution): for use in children 5 to less than 12 years of age. Labels for this formulation also have an orange border.**
- **Each formulation has specific age authorizations, storage, handling, and preparation requirements and it is important that these be reviewed carefully prior to use (see Tables 1 and 2 in the "Information for healthcare professionals" section). The formulation and lot number should be documented on patient vaccine records and for the purposes of adverse reaction reporting.**
- **Vials of COMIRNATY intended for individuals 12 years of age and older (purple cap) are not authorized to be used to prepare doses for**

**children 5 to less than 12 years of age.**

- **Vials of COMIRNATY intended for children 5 to less than 12 years of age (orange cap) should be discarded 12 hours after dilution (i.e., the first puncture). Vial labels and cartons may state that a vial should be discarded 6 hours after dilution, however, additional testing has been completed to support 12 hours of stability after dilution.**
- **Although the vaccine's brand name is now COMIRNATY, Canada will continue to receive vials of the vaccine labelled as Pfizer-BioNTech COVID-19 Vaccine. Pfizer Canada ULC is providing vaccine supplies with US Emergency Use Authorization English-only labels on the vials and cartons to expedite the global distribution of COMIRNATY.**
- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from the vial and carton labels (see the "Information for healthcare professionals" section).**
  - **The Canadian-specific labelling information, including the COMIRNATY Product Monograph and training materials, can be accessed at [CVDvaccine.ca](https://covidvaccine.ca) or [COMIRNATY.ca](https://comirnaty.ca), or by scanning the QR code on the English-only carton label. This information is also available on the federal government's [covid-vaccine.canada.ca](https://covid-vaccine.canada.ca) website. The COMIRNATY Canadian Product Monograph in French and English is also available on Health Canada's [Drug Product Database](https://drugsdb.ca) or at [pfizer.ca](https://pfizer.ca).**

### **What is the issue?**

COMIRNATY (COVID-19 Vaccine, mRNA) was issued the initial Notice of Compliance (NOC) under the Food and Drug Regulations on September 16, 2021, replacing the previous authorization under the Interim Order.

On 19 November 2021, COMIRNATY (COVID-19 Vaccine, mRNA) also received an NOC for a new formulation (DIN 02522454) to be used in children 5 to less than 12 years of age.

In addition, as an extraordinary measure to provide access to vaccine supplies in the context of the global pandemic, Pfizer and BioNTech are continuing to provide vaccine supplies with vials and cartons labelled with the name Pfizer-BioNTech COVID-19 Vaccine. This label is presented in English-only and is missing some important Canadian-specific information normally found on Health Canada approved labels (see the "Information for healthcare professionals" section).

### **Products affected**

COMIRNATY (COVID-19 Vaccine, mRNA, also referred to as Pfizer-BioNTech COVID-19 Vaccine) for Age 5 Years to <12 Years, suspension for intramuscular injection, multiple dose vials. Each vial contains 10<sup>†</sup> doses (each dose is 0.2 mL).  
DIN: 02522454

Manufacturer: BioNTech Manufacturing GmbH (Germany)  
Canadian Importer and Distributor: Pfizer Canada ULC

### **Background information**

COMIRNATY is now indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.

COMIRNATY is now authorized as two different formulations and presentations, clearly differentiated by the colour of the vial cap. Vials intended for use in children 5 to less than 12 years of age have an orange cap, and the vial labels also have an orange border.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of COMIRNATY for Age 5 Years to <12 Years with vial and carton labels that are in English-only for the current global distribution of the vaccine.

All other aspects of COMIRNATY for Age 5 Years to <12 Years with English-only labels (i.e., formulation, strength, route of administration) remain unchanged from the Health Canada authorized COMIRNATY for Age 5 Years to <12 Years. The Canadian Product Monograph for COMIRNATY, which is approved by Health Canada and available **in French and English**, should be used for complete product information.

### **Information for healthcare professionals**

COMIRNATY is now authorized as two different formulations and presentations (see Appendix A and Appendix B):

1. For individuals 12 years of age and older: **purple cap**
2. For children 5 to less than 12 years of age: **orange cap and orange border on label**

**IMPORTANT:** Each formulation has specific age authorizations, storage, handling, and preparation requirements. The differences are noted in Table 1 below and it is important that this information be carefully reviewed prior to use. The formulation

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<sup>†</sup> Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.

and lot number should be documented on patient vaccine records and for the purposes of adverse reaction reporting.

Children 5 to less than 12 years of age should be vaccinated with the vial labelled **"DILUTE PRIOR TO USE Age 5y to <12y" (orange cap)**.

Vials of COMIRNATY intended for individuals 12 years of age and older (purple cap) are not authorized to be used to prepare doses for children 5 to less than 12 years of age. Individuals 12 years and older can continue to be vaccinated with the **purple cap** presentation.

**Table 1: Important Differences between the two COMIRNATY Formulations/Presentations<sup>1</sup>**

	Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial	Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial
Vial colour	Purple Vial Cap 	Orange Vial Cap 
Age range	12 years of age and older	5 to <12 years of age
Dilution required	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	1.8 mL per vial	1.3 mL per vial
Number of doses per vial (after dilution)	6 doses per vial	10 doses per vial
Dose amount	30 micrograms per dose	10 micrograms per dose
Dose volume	0.3 mL per dose	0.2 mL per dose
Storage conditions		
ULT freezer storage time (-90 to -60°C)	Until expiry date printed on vial label	6 months after manufacturing date printed on vial label
Freezer storage time (-25 to -15°C)	2 weeks	Do not store at -25 to -15°C
Refrigerated storage time (2 to 8°C)	1 month	10 weeks
Room temperature storage time (8 to 25°C)	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture
After first puncture (2 to 25°C)	Discard after 6 hours	Discard after 12 hours <sup>†</sup>
Expiry date	Date printed on vial label <sup>‡</sup>	6 months after manufacturing date printed on vial label

ULT: Ultra-low temperature

Adapted from the COMIRNATY Product Monograph.<sup>1</sup>

<sup>†</sup> Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in the Product Monograph and here supersedes the number of hours printed on vial labels and cartons.

<sup>‡</sup> As a reminder, vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as all approved storage conditions have been maintained.

**Important reminders relating to Table 1 above:**

- Diluent: ONLY USE sterile 0.9% Sodium Chloride Injection, USP.
- 5 to <12 years of age formulation (orange cap): regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and cartons.
- The above information is subject to change, please always refer to [CVDvaccine.ca](http://CVDvaccine.ca) or [COMIRNATY.ca](http://COMIRNATY.ca) for up-to-date information.

The intended long-term storage condition for **COMIRNATY for Age 5 Years to <12 Years** is 6 months at -90°C to -60°C. The labels do not include an expiration date. Once received, frozen vials may be immediately transferred to the refrigerator, thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. The vaccine should be used within 6 months from the date of manufacture printed on the vials and cartons, as shown in the table below (also available at [CVDvaccine.ca](http://CVDvaccine.ca) and [COMIRNATY.ca](http://COMIRNATY.ca)):

**Table 2: COMIRNATY for Age 5 Years to <12 Years Expiry Information**

<b>MFG DATE</b>	<b>6 Month EXP Date</b>
08/2021	31-Jan-2022
09/2021	28-Feb-2022
10/2021	31-Mar-2022
11/2021	30-Apr-2022
12/2021	31-May-2022
01/2022	30-Jun-2022
02/2022	31-Jul-2022
03/2022	31-Aug-2022
04/2022	30-Sep-2022
05/2022	31-Oct-2022

COMIRNATY for Age 5 Years to <12 Years vials (orange cap) should be discarded 12 hours after dilution (i.e., the first puncture). Vial labels and cartons may state that a vial should be discarded 6 hours after dilution, however, additional testing has been completed to support 12 hours of stability after dilution. The information in the Product Monograph and this communication supersedes the number of hours printed on vial labels and cartons.

As previously noted, to provide timely access to COMIRNATY for Canadians, Pfizer and BioNTech will continue to provide product vials and cartons labelled in English-only for now.

Healthcare professionals are advised that:

- Canadian-specific information can be accessed on [CVDvaccine.ca](https://covid-vaccine.canada.ca) or [COMIRNATY.ca](https://covid-vaccine.canada.ca), or by scanning the QR code on carton label. This information is also available on the federal government's [covid-vaccine.canada.ca](https://covid-vaccine.canada.ca) website. The COMIRNATY Canadian Product Monograph in French and English is also available on Health Canada's [Drug Product Database](https://cdm.hc-sc.gc.ca) or at [pfizer.ca](https://pfizer.ca).
- The following important Canadian-specific information is absent from the vial and carton labels:
  - Drug Identification Number (DIN)
  - name and address of the Canadian DIN holder
  - name and address of the Canadian importer and distributor
  - all corresponding text in French
  - The "COMIRNATY" brand name
- The vial and/or carton labels for the current supplies of vaccine include the statements "*For use under Emergency Use Authorization.*" The US Food and Drug Administration (FDA) specific information (e.g., Rx only, NDC) should be disregarded as this is not relevant to the Canadian authorization.
- For any medical questions, contact Pfizer Canada ULC Medical Information at 1-800-463-6001.
- For any other general inquiries, contact Pfizer Canada ULC Customer Service at 1-833-VAX-COVI (1-833-829-2684) or email at [CanadaCSVaccine@pfizer.com](mailto:CanadaCSVaccine@pfizer.com)

### **Action taken by Health Canada**

Health Canada is permitting the use of an English-only label that reflects the US label for emergency use for a limited period. Health Canada has imposed terms and conditions requiring Pfizer Canada ULC to provide vaccine supplies with Canadian-specific labels as soon as feasible. Health Canada has made full labelling information available in French and English on the federal government's [covid-vaccine.canada.ca](https://covid-vaccine.canada.ca) website.

Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](https://recallsandsafetyalerts.gc.ca) on the Healthy Canadians Web Site. This communication update will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

## Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving COMIRNATY should be reported to Pfizer Canada ULC or your local Health Unit.

**Pfizer Canada ULC**  
**17300 Trans-Canada Highway**  
**Kirkland, QC**  
**H9J 2M5**  
[www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com)  
**Telephone: 1-866-723-7111**  
**Fax: 1-855-242-5652**

**To correct your mailing address or fax number, contact Pfizer Canada ULC Customer Service at 1-833-VAX-COVI (1-833-829-2684).**

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

For other health product inquiries related to this communication, contact Health Canada at:

Biologic and Radiopharmaceutical Drugs Directorate  
E-mail: [brdd.dgo.enquiries@hc-sc.gc.ca](mailto:brdd.dgo.enquiries@hc-sc.gc.ca)

## Original signed by

DocuSigned by:  
  
D62C6DFD49824FC...

Vratislav Hadrava M.D., Ph.D.  
Vice President & Medical Director  
Pfizer Canada ULC

## Reference

1. *COMIRNATY (COVID-19 Vaccine, mRNA)* [product monograph]. Mainz (Germany): BioNTech Manufacturing GmbH; 2021.

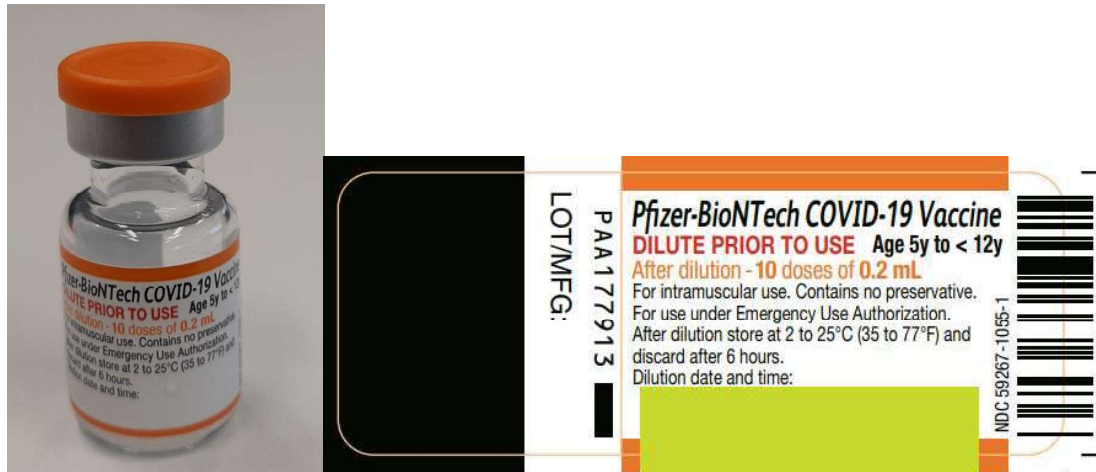


## Appendix A

### COMIRNATY (Pfizer-BioNTech COVID-19 Vaccine) for children 5 to <12 years of age

#### Vial and carton labels with English-only labelling

##### VIAL (Orange Cap)



##### **Pfizer-BioNTech COVID-19 Vaccine**

##### **DILUTE PRIOR TO USE Age 5y to <12y**

After dilution – 10 doses of 0.2 mL

For intramuscular use. Contains no preservative.

For use under Emergency Use Authorization.

After dilution store at 2 to 25°C (35 to 77°F) and discard after 6 hours.

Dilution date and time:






NDC:

Packaging no.:

LOT/MFG





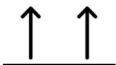
<b>CARTON TEXT</b>
<b>FRONT PANEL</b>
<p><b>Pfizer-BioNTech COVID-19 Vaccine</b>  <i>Suspension for Intramuscular Injection</i>  <b>DILUTE PRIOR TO USE</b>  <b>10 Multiple Dose Vials</b>          After dilution each vial contains          10 doses of 0.2 mL          For age <b>5</b> years to <b>&lt;12</b> years          BIONTECH                  Pfizer</p> <p>                                               </p> <p>TEAR HERE</p>
<b>TOP PANEL</b>
<p>NDC  <b>Pfizer-BioNTech</b>  <b>COVID-19 Vaccine</b>  <i>Suspension for Intramuscular Injection</i>  <b>DILUTE PRIOR TO USE</b>  <b>10 Multiple Dose Vials</b>          After dilution each vial contains 10 doses of 0.2 mL          For age <b>5</b> years to <b>&lt;12</b> years          BIONTECH                  Pfizer                                  Rx only</p>
<b>BACK PANEL</b>
<p>For storage and expiry information, see FDA-authorized Fact Sheet or scan QR code. Store in this carton to protect from light. <b>MUST BE DILUTED BEFORE USE</b> with sterile 0.9% Sodium Chloride Injection, USP (not supplied).          After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).          Discard 6 hours after dilution.          Contains no preservative.</p> <div data-bbox="863 1451 1015 1566">  </div> <p>For use under Emergency Use Authorization</p>
<b>BOTTOM PANEL</b>

Manufactured for  
BioNTech  
Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Manufactured by  
Pfizer Inc.  
New York, NY 10017

**SIDE PANEL**

**Pfizer-BioNTech**  
**COVID-19 Vaccine**  
*Suspension for*  
*Intramuscular Injection*  
**DILUTE PRIOR TO USE**

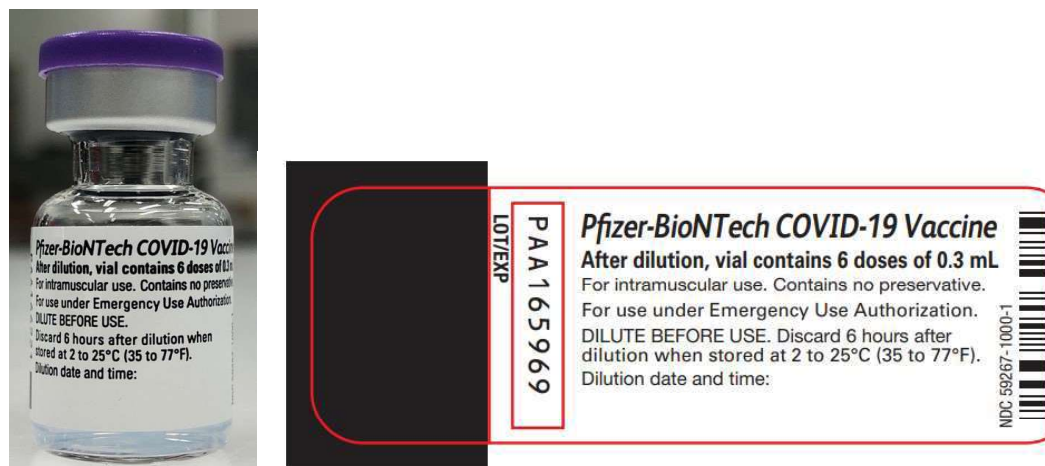
10 Multiple Dose Vials  
After dilution each  
vial contains  
10 doses of 0.2 mL  
For age 5 years to <12 years



## Appendix B

### COMIRNATY (Pfizer-BioNTech COVID-19 Vaccine) for individuals 12 years of age and older Vial and carton labels with English-only labelling

#### VIAL (Purple Cap)



#### ***Pfizer-BioNTech COVID-19 Vaccine***

**After dilution, vial contains 6 doses of 0.3 mL**



For intramuscular use. Contains no preservative.

For use under Emergency Use Authorization.

DILUTE BEFORE USE. Discard 6 hours after dilution when stored at 2 to 25°C (35 to 77°F).

Dilution date and time:

**Carton (195-Vial)**

NO COPY		NDC 59267-1000-2	
<b>Pfizer-BioNTech COVID-19 Vaccine</b> <i>Suspension for Intramuscular Injection</i> <b>195 Multiple Dose Vials</b> (after dilution each vial contains 6 doses of 0.3 mL)		Manufactured by Pfizer Inc New York, NY 10017 Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany	
			
<b>STORAGE:</b> Prior to dilution, store at -80°C to -60°C (-112°F to -76°F). Store in this carton to protect from light. <b>DOSAGE AND ADMINISTRATION:</b> After dilution, each vial contains 6 doses of 0.3 mL. See FDA-authorized Fact Sheet or scan QR code for information. <b>MUST BE DILUTED BEFORE USE</b> with sterile 0.9% Sodium Chloride Injection, USP (not supplied). After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F). Discard after 6 hours. Contains no preservative. For use under Emergency Use Authorization.		PAA166261  <b>IMPRINT AREA</b> (reads this way) <b>NO VARNISH</b> <b>NO COPY, NO INK,</b>	
NO COPY		NO COPY	
<b>Pfizer-BioNTech COVID-19 Vaccine</b> <i>Suspension for Intramuscular Injection</i> <b>195 Multiple Dose Vials</b> (after dilution each vial contains 6 doses of 0.3 mL)		<b>MUST BE DILUTED BEFORE USE</b> with sterile 0.9% Sodium Chloride Injection, USP (not supplied). After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F). Discard after 6 hours. Contains no preservative.	
<b>STORAGE:</b> Prior to dilution, store at -80°C to -60°C (-112°F to -76°F). Store in this carton to protect from light. <b>DOSAGE AND ADMINISTRATION:</b> After dilution, each vial contains 6 doses of 0.3 mL. See FDA-authorized Fact Sheet or scan QR code for information.		PAA166261  <b>IMPRINT AREA</b> (reads this way) <b>NO VARNISH</b> <b>NO COPY, NO INK,</b>	
NO COPY		NO COPY	

**CARTON TEXT****MAIN TOP PANEL**

NDC

**Pfizer-BioNTech COVID-19 Vaccine***Suspension for Intramuscular Injection***195 Multiple Dose Vials**

(after dilution each vial contains 6 doses of 0.3 mL)

Pfizer BIONTECH

**STORAGE:**

Prior to dilution, store at -80°C to -60°C (-112°F to -76°F)

Manufactured by  
Pfizer Inc

New York, NY 10017

Manufactured for BioNTech

<b><i>CARTON TEXT</i></b>	
<p>Store in this carton to protect from light.</p> <p><b>DOSAGE AND ADMINISTRATION:</b>          After dilution, each vial contains 6 doses of 0.3 mL.          See FDA-authorized Fact Sheet or scan QR code for information.          MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP (not supplied).          After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).          Discard after 6 hours.          Contains no preservative.          For use under Emergency Use Authorization.</p>	<p>Manufacturing GmbH          An der Goldgrube 12          55131 Mainz, Germany</p>
<b><i>FRONT SIDE PANEL</i></b>	
<p><b><i>Pfizer-BioNTech COVID-19 Vaccine</i></b>  <i>Suspension for Intramuscular Injection</i>  <b>195 Multiple Dose Vials</b></p> <p>(after dilution each vial contains 6 doses of 0.3 mL)</p> <p><b>STORAGE:</b>          Prior to dilution, store at -80°C to -60°C (-112°F to -76°F).          Store in this carton to protect from light.</p> <p><b>DOSAGE AND ADMINISTRATION:</b>          After dilution, each vial contains 6 doses of 0.3 mL.          See FDA-authorized Fact Sheet or scan QR code for information.</p> <p>MUST BE DILUTED BEFORE USE with sterile          0.9% Sodium Chloride Injection, USP (not supplied).          After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).          Discard after 6 hours.          Contains no preservative.          LOT/EXP:</p>	