CHLORURE DE POTASSIUM PROAMP- potassium chloride injection, solution, concentrate
Laboratoire Aguettant

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Potassium Chloride for Injection Concentrate, USP

La Jolla
Pharmaceutical

AGUETTANT
ESSENTIAL
MEDICINES

Important Prescribing Information

Subject: Temporary importation of Potassium Chloride Proamp® 0.15 g/mL (equivalent to 2 mEq/mL), concentrate for solution for infusion to address drug shortage

June, 2018

Dear Healthcare Professional,

Due to the critical shortage of Potassium Chloride for Injection Concentrate 2 mEq/mL, USP in the United States (U.S.) market, Laboratoire Aguettant (Aguettant) is coordinating with the U.S. Food and Drug Administration (FDA) to increase the availability of Potassium Chloride for Injection. Aguettant has initiated temporary importation of its Potassium Chloride Proamp® 0.15 g/mL (equivalent to 2 mEq/mL) concentrate for solution for infusion. This product is manufactured and marketed in France by Aguettant.

Given the scale of this shortage, FDA is coordinating with several firms to import Potassium Chloride for Injection 2 mEq/mL. At this time, however, no other entity except La Jolla Pharmaceutical Company is authorized by the FDA to import or distribute Aguettant's Potassium Chloride Proamp® 0.15 g/mL (equivalent to 2 mEq/mL) concentrate for solution for infusion. FDA has not approved Aguettant's Potassium Chloride Proamp® 0.15 g/mL concentrate for solution for infusion, but allows its temporary importation into the United States. You may be provided with additional letters for other imported products you receive. Please read each letter in its entirety because each letter may contain different, product-specific information.

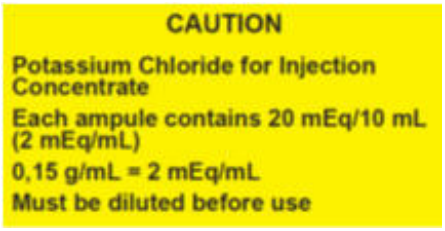
Effective immediately, and during this temporary period, Aguettant will offer the following presentation of Potassium Chloride for Injection:

Product name and description	Size	Pack factor	NDC Number
Potassium Chloride Proamp® 0.15 g/mL, concentrate for solution for infusion (equivalent to 2 mEq/mL)	10 mL	50 ampules per box	60710-015-50

There are key differences between the labeling of the FDA approved Potassium Chloride for Injection 2 mEq/mL products and Aguettant's imported Potassium Chloride Proamp® 0.15 g/mL.

It is important to note the following:

- Aguettant's product is labeled Potassium Chloride Proamp® **0,15 g/mL** which means **0.15 g/mL** in the U.S. and is equal to **2 mEq/mL** of potassium chloride. We have affixed the following sticker with this information on the carton for the imported product.



- **The ampule label of Aguettant's product is in French without English translation.** However, the carton and the prescribing information for Aguettant's product is translated into English. Institutions should develop a strategy, which may include labeling the ampules with key information, to ensure safe use of the product.
- **Aguettant's product does not contain a barcode**. Institutions should manually input the product into their systems. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.
- Inspect the solution visually for particulate matter and discoloration prior to administration.
- The imported product is packaged in polypropylene 10 mL ampules. To use the ampule, hold it upright, twist off the cap, and withdraw the solution using a syringe.

A side by side comparison of the key differences in the labeling between the FDA-approved product and the imported product is displayed in the product comparison table at the end of this letter.

Please refer to the package insert for the FDA-approved Potassium Chloride for Injection Concentrate, USP drug product for full prescribing information.

To order or if you have questions about Aguettant's Potassium Chloride Proamp® 0.15 g/mL ampules, please contact La Jolla Pharmaceutical Company at 1-800-651-3861.

To report an adverse event concerning the imported Potassium Chloride Proamp® 0.15 g/mL ampules, please contact La Jolla Pharmaceutical Company at 1-800-651-3861. Adverse events or quality problems experienced with the use of the Potassium Chloride Proamp® 0.15 g/mL ampules may also 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: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

If you have any questions about the information contained in this letter or use of Aguettant's Potassium Chloride Proamp® 0.15 g/mL ampules, please contact La Jolla's Medical Information Contact Center (MICC) at 1-800-651-3861.

Sincerely,

Jérôme JOLY Laboratoire Aguettant Director, Global QP	Cécile BAILLY Laboratoire Aguettant Medical Director	George F. Tidmarsh, MD, PhD Chief Executive Officer La Jolla Pharmaceutical Company	Doranne Frano Vice President, Regulatory Affairs La Jolla Pharmaceutical Company

PRODUCT COMPARISON TABLE

	Import Product	**U.S. Marketed Product**
	AGUETTANT	**HOSPIRA**

Presentation		
Drug Name	Potassium chloride Proamp® 0.15 g/mL, concentrate for solution for infusion	Potassium Chloride for Injection Concentrate, USP
Active Ingredient Concentration	Potassium: 2.012 mmol/mL Equivalent to: (2 mEq K+/mL) (149 mg/mL)	Each mL contains potassium chloride, 2 mEq (149 mg)
Unit Volume / Volume	10 ml polypropylene ampules The ampules are made by polypropylene compliant to the 3.1.6. European pharmacopoeia monograph. They are formed through blow fill seal process and are terminally sterilized at 121°C, assuring a maximal level of sterility of the contained solution.	5 mL single dose vials Semi-rigid plastic vials fabricated from a specially formulated polyolefin.
Indication and Usage	Concentrate for solution for infusion administered to patients suffering from low potassium blood levels (hypokalemia). Potassium is naturally present in body fluids and is needed for normal body function. It can also be used as a potassium supply for patients who are unable to be fed orally and receive total parenteral nutrition.	Potassium Chloride for Injection Concentrate, USP is indicated in the treatment of potassium deficiency states when oral replacement is not feasible.

PRINCIPAL DISPLAY PANEL - 10 mL Ampule Label

POTASSIUM chlorure PROAMP®
1,5 g - 10 mL
0,15 g/mL
2,012 mmol/mL d'ion K^+
Solution à diluer pour perfusion - IV
A diluer avant utilisation

K

15%

PRINCIPAL DISPLAY PANEL - 10 mL Ampule Box

CHLORURE DE POTASSIUM PROAMP® 0, 15 g/mL AGUETTANT
POTASSIUM CHLORIDE

CAUTION

Potassium Chloride for Injection
Concentrate

Each ampule contains 20 mEq/10 mL
(2 mEq/mL)

0,15 g/mL = 2 mEq/mL

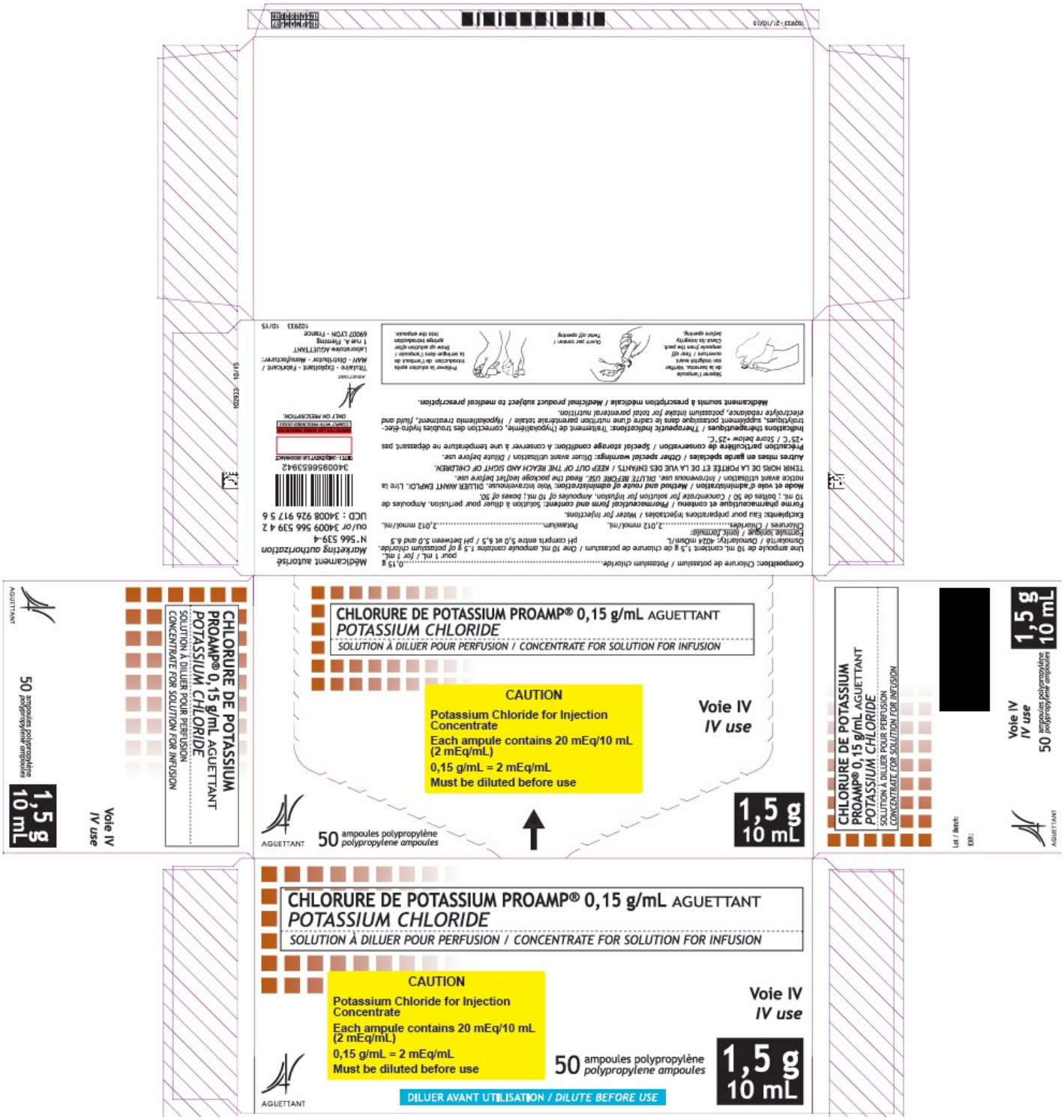
Must be diluted before use

IV use

AGUETTANT

50
polypropylene ampoules

1,5 g
10 mL



CHLORURE DE POTASSIUM PROAMP

potassium chloride injection, solution, concentrate

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:60710-015
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
potassium chloride (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	potassium chloride	0.15 g in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60710-015-50	50 in 1 BOX	07/31/2018	
1		10 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug for use in drug shortage		07/31/2018	

Labeler - Laboratoire Aguettant (267584998)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoire Aguettant		271085545	MANUFACTURE(60710-015) , ANALYSIS(60710-015) , LABEL(60710-015) , PACK(60710-015) , STERILIZE(60710-015) , RELABEL(60710-015)

Revised: 8/2018 Laboratoire Aguettant