

April 8, 2022

### IMPORTANT DRUG INFORMATION

**Subject: Dropper Temporarily Unavailable for Fluphenazine HCl Oral Solution (Concentrate) USP, 5 mg/mL**

Dear Healthcare Provider,

Pharmaceutical Associates, Inc. (PAI) would like to advise you of a temporary unavailability of the calibrated droppers typically provided in each carton of Fluphenazine HCl Oral Solution (Concentrate) USP, 5 mg/mL. PAI is working in conjunction with the U.S. Food and Drug Administration to ensure continued supply of Fluphenazine HCl Oral Solution (Concentrate) USP, 5 mg/mL during this dropper component shortage. Although the carton states, “with calibrated dropper,” due to the ongoing shortage of dropper components and assembled droppers, PAI is providing the drug product without a dropper to accompany the 118 mL (4 oz.) bottle of Fluphenazine HCl Oral Solution. Once the component shortage is resolved, PAI plans to provide a new dropper with each bottle of drug product again.

The Fluphenazine HCl Oral Solution is provided in a 5 mg/mL concentration. The dosing chart below provides a dose equivalence in **mg** of drug and **mL** of drug to aid dosing using a typical oral syringe or any device capable of measuring 1 mL in increments of 0.1 mL units. If the Healthcare Provider or Patient has a current Fluphenazine HCl Oral Solution (Concentrate) dropper (from a previous prescription), they may safely continue to use the dropper to administer doses of this medication. If no calibrated Fluphenazine HCl Oral Solution (Concentrate) dropper is currently available, a suitable oral syringe with a minimum of 1 mL capacity and marked increments of 0.1 mL (each 0.1 mL is equivalent to 0.50 mg of drug) may be used to safely dose Fluphenazine HCl Oral Solution (Concentrate) in accordance with the dosing chart shown below.

***Table 1 Fluphenazine HCl Oral Solution (Concentrate) 5 mg/mL Dosing***

Calibration marks in <b>mg</b> of Fluphenazine HCl Concentrate 5 mg/mL	Calibration marks in <b>mL</b> of Fluphenazine HCl Concentrate 5 mg/mL
0.50 mg	0.1 mL
1 mg	0.2 mL
2 mg	0.4 mL
3 mg	0.6 mL
4 mg	0.8 mL
5 mg	1 mL

Healthcare Providers and caregivers should ignore the statement “Before Dispensing, Replace Cap With Safety Cap Dropper” on the container label and carton labeling, and use the closure which comes on the bottle of drug product to reseal the bottle after each dose is administered.

PAI expects the shortage of dropper components to be a temporary event. PAI plans to begin providing the new dropper to accompany the Fluphenazine HCl Oral Solution (Concentrate) USP, 5 mg/mL as soon as possible.

### **Reporting Adverse Events**

Adverse events or quality problems experienced with the use of this product 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/medwach/report.htm](http://www.fda.gov/medwach/report.htm)
- Regular mail or fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://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 (1-800-332-0178).

If you have any questions about the dosing information provided for Fluphenazine HCl Oral Solution (Concentrate) USP, 5 mg/mL or any other medical inquiries, please contact PAI at 1-800-845-8210 or at [www.paipharma.com](http://www.paipharma.com). Once the dropper component shortage has resolved, PAI will resume distributing the drug product with a new dropper-closure provided in the carton just as before the component shortage began.

Sincerely,



Digitally signed by  
TBolton@PAIPHARMA.COM  
Date: 2022.04.08 13:36:03  
-04'00'

Tom Bolton

Director of Regulatory Affairs and Compliance

Pharmaceutical Associates, Inc.