



07 SEP 2021

FDA ADVISORY
No. **2021-2263**

TO : ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

SUBJECT : Public Health Warning Against the Purchase and Use of the following Verified Counterfeit Drug Products:

1. Carbocisteine (Solmux®) 500 mg Capsule
2. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg/2 mg/500 mg Film-Coated Tablet
3. Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg/2 mg/500 mg Tablet
4. Loperamide (Diatabs®) 2 mg Capsule
5. Mefenamic Acid (Dolfenal®) 500 mg Film-Coated Tablet
6. Paracetamol (Biogesic®) 500 mg Tablet
7. Aluminum Hydroxide / Magnesium Hydroxide / Simeticone (Kremil-S®) 178 mg / 233 mg / 30 mg Chewable Tablet
8. Ibuprofen (Medicol® Advance) 200 mg Softgel Capsule
9. Hyoscine N-butylbromide (Buscopan®) 10 mg Tablet
10. Ibuprofen / Paracetamol (Alaxan® FR) 200 mg / 325 mg Capsule
11. Meclizine HCl (Bonamine*) 25 mg Chewable Tablet
12. Loperamide HCl (Lomotil®) 2 mg Tablet
13. Dexamethasone (Decilone® Forte) 4 mg Tablet
14. Loperamide (Imodium) 2 mg Capsule



The Food and Drug Administration (FDA) advises the public against the purchase and use of the counterfeit version of the following products:



Figure 1. Comparison between the Authentic and Counterfeit Carbocisteine (Solmux®) 500mg Capsule (Lot nos. U089512, U182208, and U011221)

AUTHENTIC



COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 2. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Bioflu®) 10 mg/2 mg/500 mg Film-Coated Tablet (Lot nos. U091223 and U201710)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 3. Comparison between the Authentic and Counterfeit Phenylephrine HCl / Chlorphenamine Maleate / Paracetamol (Neozep® Forte) 10 mg/2 mg/500 mg Tablet (Lot nos. 13127758 and 20110411)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 4. Comparison between the Authentic and Counterfeit Loperamide (Diatabs®) 2 mg Capsule (Lot nos. U032570, U113766, and U092468)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 5. Comparison between the Authentic and Counterfeit Mefenamic Acid (Dolifenal[®]) 500 mg Film-Coated Tablet (Lot no. M058520)

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COUNTERFEIT



Counterfeit – Logo, security mark, knurling, print color and appearance are different from standard.

Figure 6. Comparison between the Authentic and Counterfeit Paracetamol (Biogesic®) 500 mg Tablet (Lot no. 25180922)