

## 1. NORMALIZE THE OBSERVATION OF THE NEGATIVE EVENT

### FDA Drug Safety Communication

### **FDA warns of serious skin reactions with the use of constipation medication, DRUG A**

#### **Safety Announcement**

The U.S. Food and Drug Administration (FDA) is warning that DRUG A, used to treat constipation, has been associated with a risk of serious skin reactions. We are requiring a warning about this risk to be added to the label of DRUG A.

Patients who develop a skin rash or reaction while using DRUG A should seek medical attention right away. These reactions can occur with first-time use of DRUG A or at any time while it is being taken, and can be life-threatening. **It is important to know that all drugs have risks as well as benefits.** Patients who have experienced a skin reaction with DRUG A should contact their health care professional to discuss alternative constipation medicines.



U.S. Food and Drug Administration  
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## Drug Safety Communications

### 2. PROVIDE ADDITIONAL INSTRUCTIONS

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Patients who develop a skin rash or reaction while using DRUG A should seek medical attention right away. These reactions can occur with first-time use of DRUG A or at any time while it is being taken, and can be fatal. **Talk to your health care professional if you have questions or concerns about the risks of the drug.** Patients who have experienced a serious skin reaction with DRUG A should contact their health care professional to discuss alternative constipation medicines.



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### 3. PROVIDE ADDITIONAL INFORMATION ON SIGNS/ SYMPTOMS OF AN ADVERSE EVENT OF SIDE EFFECT

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Patients who develop a skin rash or reaction while using DRUG A should seek medical attention right away. **Reddening of the skin, rash, blisters, and detachment of the upper surface of the skin can occur with the use of DRUG A.** These reactions can occur with first-time use of DRUG A or at any time while it is being taken. Patients who have experienced a serious skin reaction with DRUG A should contact their health care professional to discuss alternative constipation medicines.

## 4. NONE – CONTROL

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Patients who develop a skin rash or reaction while using DRUG A should seek medical attention right away. These reactions can occur with first-time use of DRUG A or at any time while it is being taken. Patients who have experienced a serious skin reaction with DRUG A should contact their health care professional to discuss alternative constipation medicines.