



U.S. Food and Drug Administration
Protecting and Promoting Your Health

Drug Safety Communications

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.



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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.



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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.