

AZADROX RX WOUND GEL- dressing, wound, drug
Alvix Laboratories, LLC

AzaDrox Rx Wound Gel

DESCRIPTION

AzaDrox™ Rx Wound Gel is a wound dressing hydrogel that helps maintain a moist wound environment that is conducive to healing by either absorbing or donating moisture and wound exudates.

INDICATIONS FOR USE

AzaDrox™ Rx Wound Gel is indicated for use in the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites and donor sites.

PRECAUTIONS

1. Always use AzaDrox™ Rx Wound Gel exactly as indicated by the prescribing physician. Consult with a healthcare professional if you have any concerns or questions about the wound.
2. Always be alert for signs of wound infection or worsening conditions. These can include:
 - Pus or cloudy fluid draining from the wound
 - Increased redness around the wound
 - Wound has become extremely tender
 - Increased pain or swelling 48 hours after wound occurred
 - Onset of fever
3. The gel is designed for use on any part of the body except for oral and ophthalmic use. Do not use the gel in any other manner.

HOW TO APPLY

Home use of AzaDrox™ Rx Wound Gel should only be allowed if indicated by the prescribing physician. Always use AzaDrox™ Rx Wound Gel exactly as indicated by the prescribing physician.

1. Wash your hands with soap and water before touching the wound.
2. Carefully clean the wound using soap and water, or as otherwise indicated by the prescribing physician.
3. Dispense gel onto appropriate clean applicator (such as a tongue depressor or gauze) in a sufficient amount to liberally cover the wound. Cover the gel if desired with a secondary cover such as a gauze dressing wrap, film, or non-woven adhesive secondary dressing.
4. Remove product from the skin within 24 hours by leaning the wound site with soap and water.
5. Discard remaining product.

INGREDIENTS

Deionized water, carbopol, silver as nanoparticles, urea (less than 1%), sodium hydroxide

HOW SUPPLIED

AzaDrox™ Rx Wound Gel is supplied in a carton containing 20 single-use 5 mL sachets. 1545595703 (GTIN: 00315455957039)

PRESCRIPTION MEDICAL DEVICE: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

STORE AT ROOM TEMPERATURE

Keep this and other similar products out of the reach of children.

Alvix Laboratories, LLC

Ocean Springs, MS 39564

1 888 526 5449

AzaDrox™ Rx Wound Gel Package Insert

INDICATIONS FOR USE

AzaDrox™ Rx Wound Gel is indicated for use in the management of 1st and 2nd degree burns, wounds such as strain ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites and donor sites.

PRECAUTIONS

- Always use AzaDrox™ Rx Wound Gel exactly as indicated by the prescribing physician. Consult with a healthcare professional if you have any concerns or questions about the wound.
- Always be alert for signs of wound infection or worsening condition. These can include:
 - Pain or cloudy fluid draining from the wound
 - Increased redness around the wound
 - Wound has become extremely tender
 - Increased pain or swelling 48 hours after the wound occurred
 - Onset of fever
- The gel is designed for use on any part of the body except for oral and ophthalmic use. Do not use the gel in any other manner.

**PRESCRIPTION MEDICAL DEVICE:
FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN**

STORE AT ROOM TEMPERATURE

Keep this and other similar products out of the reach of children.

HOW TO APPLY

Correct use of AzaDrox™ Rx Wound Gel should only be allowed if indicated by the prescribing physician. Always use AzaDrox™ Rx Wound Gel exactly as indicated by the prescribing physician.

- Wash your hands with soap and water before touching the wound.
- Carefully clean the wound using soap and water, or as otherwise indicated by the prescribing physician.
- Dispense the gel onto an appropriate clean applicator (such as a tongue depressor or gauze) in a sufficient amount to liberally cover the wound. Cover the gel if desired with a secondary cover such as a gauze dressing wrap, film or non-adhesive secondary dressing.
- Remove product from skin within 24 hours by cleaning the wound site with soap and water.
- Discard remaining product.

INGREDIENTS

Deionized water, carbopol, silver as nanoparticles, urea (less than 1%), sodium hydroxide.

HOW SUPPLIED

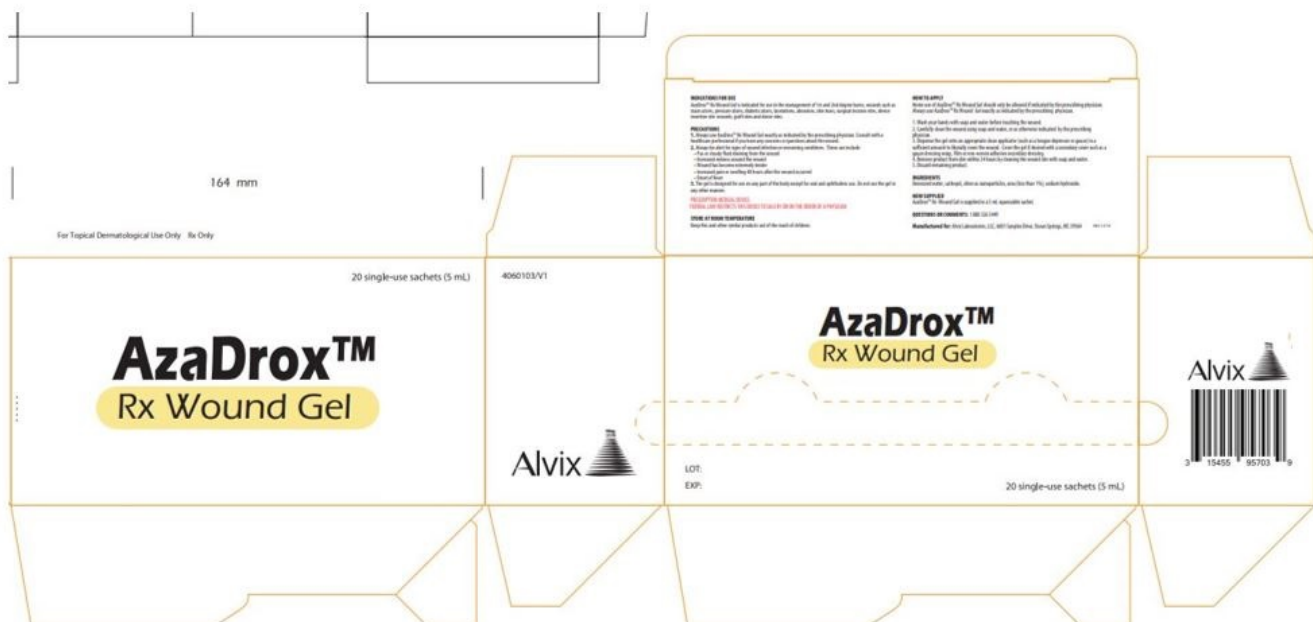
AzaDrox™ Rx Wound Gel is supplied in a 5 mL squeezable sachet.

QUESTIONS OR COMMENTS: 1 888 526 5449

Manufactured for: Alvix Laboratories, LLC, 6601 Sapphire Drive, Ocean Springs, MS 39564

REV 1.2/19

AzaDrox™ Rx Wound Gel Primary Label



AZADROX RX WOUND GEL

dressing, wound, drug

Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	GS1:00315455957039
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	GS1:00315455957015	5 in 1 PACKET		
1	GS1:00315455957039	100 mL in 1 CARTON; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K162017	05/18/2020	

Labeler - Alvix Laboratories, LLC (962445925)

Revised: 5/2020

Alvix Laboratories, LLC