

OMNI-STAT® Hemostatic agent

Information leaflet

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FOR TEMPORARY TOPICAL CONTROL OF LIGHT, MODERATE AND SEVERE BLEEDING

OMNI-STAT® Hemostatic Granules (3g)

Indications:

OMNI-STAT for minor external bleeding from wounds and procedures (Rx) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

OMNI-STAT for moderate to severe external bleeding wounds (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.

Directions for Use:

1. Tear open OMNI-STAT 3g pouch.
2. Blot away any excess blood or exudate from the wound.
3. Pour enough OMNI-STAT onto the wound to cover the entire bleeding area. OMNI-STAT should be applied directly to the source of bleeding.
4. Quickly cover with gauze and apply firm pressure for 1 to 3 minutes depending on the severity of the bleeding.
5. If bleeding continues apply pressure for 3 more minutes. If further OMNI-STAT is required use an additional pouch.
6. Five minutes after bleeding has stopped, gently remove any excess OMNI-STAT. Use saline if required
7. Discard any unused OMNI-STAT.

Removal instructions:

At first dressing change after use, OMNI-STAT should be cleansed and removed from the wound using your standard wound cleansing protocols. If required OMNI-STAT can be removed (physically) and then any residual irrigated away with water or saline.

Warnings

For external use only. Do not eat. Do not apply over eyes. Contains chitosan from shrimp shells. Allergy studies show no adverse reaction. Data on file at Omni-stat Medical Inc. For single use only. Do not resterilize.

OMNI-STAT® Hemostatic Gauze (4in. x 4in.)

Indications:

OMNI-STAT Hemostatic Gauze for minor external bleeding from wounds and procedures (Rx) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

OMNI-STAT Hemostatic Gauze for moderate to severe external bleeding wounds (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.

Directions for Use:

1. Tear open OMNI-STAT gauze pack.
2. Blot away any excess blood or exudate from the wound.
3. Apply pre-folded OMNI-STAT onto the wound to cover the entire bleeding area. OMNI-STAT should be applied directly to the source of bleeding. If bleeding source is below the wound surface, then OMNI-STAT gauze can be unfolded and tightly packed into wound.
4. Apply firm pressure for 1 to 3 minutes depending on the severity of the bleeding.
5. If bleeding continues apply pressure for 3 more minutes. If OMNI-STAT gauze becomes saturated then use an additional OMNI-STAT gauze pack.
6. OMNI-STAT gauze can be gently removed after 5 minutes. Use saline if required.
7. Discard any unused OMNI-STAT.

Removal instructions:

At first dressing change after use, OMNI-STAT should be cleansed and removed from the wound using standard wound cleansing protocols. If required OMNI-STAT should be soaked with saline prior to removal (physically) and then any residual irrigated away with water or saline.

Warnings

For external use only. Do not eat. Do not apply over eyes. Contains chitosan from shrimp shells. Allergy studies show no adverse reaction. Data on file at Omni-Stat Medical Inc. For single use only. Do not resterilize.

How does OMNI-STAT™ work?

Applying OMNI-STAT to a wound prevents blood loss by forming a gel-like plug.

OMNI-STAT's clotting action is independent of the body's normal clotting process. It has been shown to work in the presence of common anti-coagulants such as warfarin and heparin.

OMNI-STAT is made using chitosan, a natural polysaccharide.

OMNI-STAT (chitosan granules) has been proven in controlled trials to stop major arterial bleeding within 3 mins and reduce blood loss.

Kozen BG, Kircher SJ, Henao J, et. al. An alternative hemostatic dressing: comparison of Celox, HemCon, and QuikClot. Acad Emerg Med. 2008; 15: 74–81.

Laboratory testing has shown OMNI-STAT to be effective in blood temperatures down to 56 deg F.

www.OMNI-STAT.com