

## DE GEBRUCHSANWEISUNG

### Actinol® Solution Plus

#### Lösung zur Reinigung, Spülung, Befeuchtung und Pflege von Wunden

Actinol® Solution Plus ist eine Reinigungs-, Spül-, Befeuchtungs- und Pflegelösung, die zusammen mit Materialien wie Bandagen, Verbänden, Pads und Wundfüllern für akute, chronische und infizierte Wunden sowie Verbrennungen 1. und 2. Grades verwendet wird. Actinol® Solution Plus reinigt Wunden mechanisch. Oberflächenaktive Mittel in ihrer Zusammensetzung sorgen für eine bequeme und schmerzlose Reinigung, die vor der Wundversorgung benötigt wird, indem die Oberflächenspannung verringert wird, indem es eine Spül- und Wundheilungsprozess bei, Actinol® Solution Plus sehr positive Reinigungs- und Feuchtigkeitwirkung an den aufgetragenen Stellen gewährleistet.

Actinol® Solution Plus kann auch zur antiseptischen Reinigung und Einweichung von Verbandsmaterialien verwendet werden. Getrocknete und auf die Wunde geklebte Bandagen und Verbände können vor dem Entfernen mit Actinol® Solution Plus benetzt werden, so dass die durch abgelagerten Mikroorganismen besetzt, und sie leicht entfernt werden können, ohne dass die Wunde sekundär traumatisiert wird. Die antimikrobielle Wirkung von Actinol® Solution Plus bietet eine ideale Lösung, um die Bildung von Biofilmen auf Bandagen und Verbänden zu verhindern.

Actinol® Solution Plus hemmt weder die Granulation noch die Epithelisierung. Es hat weder reizende noch schmerzgebende Eigenschaften. Es verursacht keine Sensibilisierung und kann über einen langen Zeitraum sicher verwendet werden. Der Inhaltstoff Polyhexanid ist klinisch millionenfach bewährt, dermatologisch unbedenklich und gilt als Wundbehandlungsmittel der ersten Wahl<sup>1</sup>. Für einen gesunden Wundheilungsprozess sollte in regelmäßigen Abständen eine Wundreinigung und Pflege durchgeführt werden.

<sup>1</sup>Wissenschaftliche Empfehlung der Deutschen Gesellschaft für Wundheilung und Wundmanagement e.V. (DgWfW) 2004 & 2009.

#### Indikationen

- Infizierte oder nicht infizierte akute Wunden (z.B. traumatische Wunden, die durch Schmitte, Risse, Abschürfungen, Quetschungen, Bisswunden, Stichwunden usw. entstanden sind oder chirurgische Wunden),
  - Infizierte oder nicht infizierte chronische Wunden (z.B. diabetische Geschwüre, venöse Geschwüre, Dekubitus (Druckstellen), usw.),
  - Infizierte oder nicht infizierte tiefe Wunden (z.B. Verbrennungen ersten und zweiten Grades, chemische Verbrennungen, usw.),
  - Wunden, verursacht durch elektrischen Strom, Strahlungsunden,
  - Eingangsregionen von urologischen Kathetern.
  - Pflege von peristomalen Haut, Fisteln und Abszessen,
  - Geeignet zur Reinigung und Pflege von Wundoberflächen vor dem Anlegen von Verbänden, sowie Anwendung gegen Infektion, Erweichung und Entfernung von Verbandmaterialien, z.B. Bandagen, Verbänden, Wundauflagen und Wundfüllern, die getrocknet, kontaminiert und an der Wunde angehaftet sind.
  - Gebrauchsanweisung
- Actinol® Solution Plus sollte vor jeder Behandlung zur Reinigung und Spülung von Wundoberfläche verwendet werden. Actinol® Solution Plus kann in Kombination mit Actinol® Gel Plus angewendet werden. Die Wunde sollte vor der Anwendung von Actinol® Gel Plus mit Actinol® Solution Plus gereinigt werden, um Verunreinigungen und Ablagerungen zu entfernen. Mit Actinol® Solution Plus getränkte Bandagen, Verbände, Binden etc. können zur Wundreinigung verwendet werden.

Actinol® Solution Plus kann auch zur antiseptischen Reinigung und Aufweichung von verkrusteten Verbandsmaterialien verwendet werden, die getrocknet und an der Wundoberfläche haften und schwer zu entfernen sind.

Actinol® Solution Plus erreicht die vertretbareste Hygiene. Bei Brüngen, bei denen die Wunde mit Actinol® Solution Plus gereinigt werden, um Verunreinigungen und Ablagerungen zu entfernen. Mit Actinol® Solution Plus getränkte Bandagen, Verbände, Binden etc. können zur Wundreinigung verwendet werden.

Actinol® Solution Plus kann auch zur antiseptischen Reinigung und Aufweichung von verkrusteten Verbandsmaterialien verwendet werden, die getrocknet und an der Wundoberfläche haften und schwer zu entfernen sind.

Actinol® Solution Plus kann auch zur antiseptischen Reinigung und Aufweichung von verkrusteten Verbandsmaterialien verwendet werden, die getrocknet und an der Wundoberfläche haften und schwer zu entfernen sind.

Actinol® Solution Plus kann auch zur antiseptischen Reinigung und Aufweichung von verkrusteten Verbandsmaterialien verwendet werden, die getrocknet und an der Wundoberfläche haften und schwer zu entfernen sind.

Actinol® Solution Plus kann auch zur antiseptischen Reinigung und Aufweichung von verkrusteten Verbandsmaterialien verwendet werden, die getrocknet und an der Wundoberfläche haften und schwer zu entfernen sind.

## 93/42/EEG und den Änderungen 2007/47/EG.

### Zusammensetzung: Poloxamer, Polyhexamethylenbiguanid (PHMB, 0,1%) und Hilfsstoffe.

#### Aussehen und Geruch: Klare, farblose und fast geruchlose Lösung.

**Haltbarkeit:** Bitte beachten Sie das Verfallsdatum. Verschleißen Sie die Kappe dicht und lagern Sie es in einer kühlen, trockenen und frostfreien Umgebung auf. Die Haltbarkeit beträgt 2 (zwei) Jahre bei Raumtemperatur. Angerobene Flasche nicht über 35 °C lagern. Verbrauchen Sie das geöffnete Produkt innerhalb von 8 (acht) Wochen.

### INSTRUCTIONS FOR USE

#### Actinol® Solution Plus

#### Cleaning, irrigation, moistening and care solution for wounds

Actinol® Solution Plus is a cleaning, irrigation, moistening and care solution used together with materials such as bandages, dressings, pads and wound fillers for acute, chronic and infected wounds as well as 1<sup>st</sup> and 2<sup>nd</sup> degree burns.

Actinol® Solution Plus cleans wounds mechanically. Surface active agents in its composition provide a convenient and painless cleaning needed before wound care by decreasing the surface tension. Actinol® Solution Plus contributes to the wound healing process by ensuring a highly positive cleansing and moisturizing effect on applied areas.

Actinol® Solution Plus can also be used for antiseptic cleansing and softening of dressing materials. Bandages and dressings dried and adhered to the wound can be wetted by Actinol® Solution Plus before removal, so the microorganisms settled on them can be eliminated and they can be easily removed without causing any secondary trauma to the wound. The antimicrobial effect of Actinol® Solution Plus offers an ideal solution to prevent biofilm formation on bandages and dressings.

Actinol® Solution Plus does not inhibit granulation or epithelialization. It has neither irritating nor pain giving properties. It causes no sensitization and can be used safely for a long time. The ingredient polyhexanide is millionfold clinically proven, dermatologically harmless and is considered to be the first choice as wound treatment agent<sup>1</sup>.

<sup>1</sup>For a healthy wound recovery process, wound cleaning and care should be performed in regular intervals.

<sup>1</sup>Consensus recommendation of the German Society for Wound Healing and Wound Management e.V. (DgWfW) 2004 & 2009.

#### Indications

- Infected or uninfected acute wounds (e.g. traumatic wounds that occur as the result of cuts, tears, excoriations, crushing, being bitten, being stung, etc.)
- Infected or uninfected chronic wounds (e.g. diabetic ulcers, venous ulcers, decubitus (pressure sores), etc.),
- Infected or uninfected thermal or chemical wounds (e.g. 1<sup>st</sup> and 2<sup>nd</sup> degree burns, chemical burns, etc.),
- Wounds that caused by electrical current,
- Radiation wounds,
- Entry regions of urological catheters,
- Maintenance of peristomal skin, fistulas and abscesses,
- Suitable for cleaning and maintenance of wound surface prior to dressing.

Actinol® Solution Plus should be used for wound surface cleaning and irrigation before any treatment. Actinol® Solution Plus can be applied in combination with Actinol® Gel Plus. The wound should be cleaned with Actinol® Gel Plus to remove any contaminants and deposits. Bandages, dressings, pads etc. soaked in Actinol® Solution Plus can be used to clean wounds.

Actinol® Solution Plus can also be used for antiseptic cleansing and softening of encrusted dressing materials that are dried and adhered to the wound surface and difficult to remove. Actinol® Solution Plus softens the encrusted bandage and dressing, while eliminating the pathogenic microorganisms that have settled on them and prevents the wound from being infected.

Actinol® Solution Plus can be applied directly onto the wound as well as onto the bandage and gauzes. Materials

## such as bandage, gauze, wiping clothes, etc. should not be used again. Actinol® Solution Plus can be heated to body temperature prior to use.

### Usage with dressings and bandages

Thoroughly wet dressings and bandages adhered to the wound surface with Actinol® Solution Plus, wait ca. 5-10 min. For softening and remove them carefully from wound. In order to maintain a moist wound climate, the dressing can be changed daily, if necessary, several times a day. Actinol® Solution Plus is compatible with all modern wound dressings.

### Catheter care

Possible infections can be avoided by regular cleaning catheter inlet ports, flexible connectors and its environment by Actinol® Solution Plus. Spray Actinol® Solution Plus on the area from a short distance and wait ca. 1-5 min. The ingredients of Actinol® Solution Plus are particularly mucous membrane-friendly, cleanse catheter and PEG material without damaging it. As with wound care, encrusted sticking plasters can be removed easily after wetting with Actinol® Solution Plus.

Side Effects Actinol® Solution Plus contains polyhexanide. Even though it is not irritating, it can cause allergic reactions in the bands and the patient's hands. Actinol® Solution Plus is reported that polyhexanide may cause an anaphylactic shock in rare cases (less than 1 out of 10,000). When allergic skin testing is recommended should not use. Patients hypersensitive to polyhexanide should not use the product. The biocompatibility index of Actinol® Solution Plus is found to be >1 and has a high tissue compatibility. Actinol® Solution Plus may cause allergic reactions such as itching (urticaria) and rash (eczema). In very rare cases, a mild burning sensation may occur after application of Actinol® Solution Plus, however this sensation disappears in a couple of minutes.

**Contraindications** Actinol® Solution Plus in the following cases: It is not suitable for use in the cartilage and aseptic joint surgeries, in the middle and internal ear and in the eye (Actinol® Solution Plus contacts the aseptic cartilage, wash immediately with Ringer solution or physiological saline solution).

- If the patient is known or suspected to be hypersensitive to any of the ingredients,
- On central nervous system or meningis,
- Along with anionic surfactants, cleansing soaps, creams, oils, enzymes, etc. These substances should be removed fully from the wound surface before use.
- For peritoneal lavage and washing,
- It should not be used in the first four months of pregnancy. Depending on the risk-benefit ratio, it should be used later in pregnancy should be evaluated according to the doctor's recommendation.

**Warnings and Precautions** Read the instructions carefully before use. Only for external application onto skin. Do not use for infusion or injection purposes. Do not swallow! Keep out of reach of children. Do not use if the sealing under the cap is torn or broken. Close the bottle immediately after use to avoid any contamination. The rim of the bottle should be protected from direct contact to avoid contamination while using. Bottles, which directly contact the wound or are contaminated in some other ways should be disposed. Keep only in original packaging contact from sunlight. Dispose according to local regulations.

**For newborns and infants:** Due to the insufficiency of clinical information, Actinol® Solution Plus should be used only under a strict and close medical supervision on newborns and infants.

This product is a Class II Medical Device according to the 93/42/EEC and the 2007/47/EC amendments.

**Ingredients:** Poloxamer, Polyhexamethylene biguanide (PHMB, 0.1%) and excipients.

**Appearance and odor:** Clear, colorless and almost odorless solution.

**Shelf life:** Please see the expiry date. Close the cap tightly and store in a cool, dry and frost-free environment. Shelf life is 2 (two) years at room temperature. Do not store an opened bottle above 35 °C. Consume the open product within 8 (eight) weeks.

**DE MODE D'EMPLOI**

**Actinol® Solution Plus**

Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des plaies. Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des plaies à utiliser avec du matériel tel que des bandes, des pansements, des compresses et du matériel de remplissage des plaies pour les plaies aiguës, chroniques et infectées ainsi que les brûlures au 1<sup>er</sup> et 2<sup>nd</sup> degré. Actinol® Solution Plus nettoie mécaniquement les plaies. Elle contient des agents tensioactifs qui permettent un nettoyage des plaies pratique et indolore sans pour le traitement afin de réduire la tension de surface. Actinol® Solution Plus contribue au processus de cicatrisation des plaies en apportant aux zones traitées un effet nettoyant et hydratant très positif. Actinol® Solution Plus detegre le ferre mecanicamente. L'ensioactivo presenti nella sua composizione permettono la detersione comoda e indolore necessaria prima del trattamento della ferita. Actinol® Solution Plus facilita el proceso de curación de la herida al garantizar un efecto de limpieza y humectación muy positivo en las áreas de aplicación. Actinol® Solution Plus puede usarse también para la limpieza y el ablandado antisépticos de los materiales del apósito. Actinol® Solution Plus también puede ser utilizado para la limpieza antiséptica y suavización de los materiales de curativo. Ligaduras y pensos secos y colados a ferida podem ser humedecidos com o Actinol® Solution Plus antes da remoção, de modo que os microorganismos nes estabelecidos possam ser eliminados e eles possam ser removidos com facilidade sem provocarem traumas secundários na ferida. O efeito antimicrobiano do Actinol® Solution Plus oferece uma solução ideal para evitar a formação de biofilmes em ligaduras e pensos. Actinol® Solution Plus não impede a granulação ou epitelização. Não irrita nem causa dor. Não provoca sensibilização e pode essere utilizzato a sicurezza per un lungo periodo di tempo. La polissanide presente nella sua composizione è stata clinicamente testata milioni di volte, è dermatologicamente innocua e considerata agente di prima scelta per il trattamento delle ferite. Per un sano processo di guarigione, la detersione e il trattamento della ferita devono essere effettuati a intervalli regolari. "Recomendación de consenso de la Asociación Alemana para la Curación y el Tratamiento de Heridas (DgWfW) en 2004 y 2009.

**Indicazioni**

- Plaies aiguës infectées ou non (p. ex. plaies traumatiques dues à une coupure, déchirure, morsure, écorchure, éraecement, morsure, piqûre, etc., ou plaies chirurgicales),
- Plaies chroniques infectées ou non (p. ex. ulcères diabétiques, ulcères veineux, escarres, etc.),
- Plaies thermiques ou chimiques infectées ou non (p. ex. brûlure au 1<sup>er</sup> et 2<sup>nd</sup> degré, brûlure chimique, etc.),
- Plaies causées par un courant électrique,
- Plaies d'irradiation,
- Points d'entrée de cathéters urologiques,
- Entretien de la peau péri-stomale, des fistules et des abcès,
- Convient au nettoyage et à l'entretien de la surface de la plaie avant de poser un pansement.

Actinol® Solution Plus should be used for wound surface cleaning and irrigation before any treatment. Actinol® Solution Plus can be applied in combination with Actinol® Gel Plus. The wound should be cleaned with Actinol® Gel Plus to remove any contaminants and deposits. Bandages, dressings, pads etc. soaked in Actinol® Solution Plus can be used to clean wounds.

Actinol® Solution Plus can also be used for antiseptic cleansing and softening of encrusted dressing materials that are dried and adhered to the wound surface and difficult to remove. Actinol® Solution Plus softens the encrusted bandage and dressing, while eliminating the pathogenic microorganisms that have settled on them and prevents the wound from being infected.

Actinol® Solution Plus can be applied directly onto the wound as well as onto the bandage and gauzes. Materials

such as bandage, gauze, wiping clothes, etc. should not be used again. Actinol® Solution Plus can be heated to body temperature prior to use.

Usage with dressings and bandages Thoroughly wet dressings and bandages adhered to the wound surface with Actinol® Solution Plus, wait ca. 5-10 min. For softening and remove them carefully from wound. In order to maintain a moist wound climate, the dressing can be changed daily, if necessary, several times a day. Actinol® Solution Plus is compatible with all modern wound dressings.

Catheter care Possible infections can be avoided by regular cleaning catheter inlet ports, flexible connectors and its environment by Actinol® Solution Plus. Spray Actinol® Solution Plus on the area from a short distance and wait ca. 1-5 min. The ingredients of Actinol® Solution Plus are particularly mucous membrane-friendly, cleanse catheter and PEG material without damaging it. As with wound care, encrusted sticking plasters can be removed easily after wetting with Actinol® Solution Plus.

Side Effects Actinol® Solution Plus contains polyhexanide. Even though it is not irritating, it can cause allergic reactions in the bands and the patient's hands. Actinol® Solution Plus is reported that polyhexanide may cause an anaphylactic shock in rare cases (less than 1 out of 10,000). When allergic skin testing is recommended should not use. Patients hypersensitive to polyhexanide should not use the product. The biocompatibility index of Actinol® Solution Plus is found to be >1 and has a high tissue compatibility. Actinol® Solution Plus may cause allergic reactions such as itching (urticaria) and rash (eczema). In very rare cases, a mild burning sensation may occur after application of Actinol® Solution Plus, however this sensation disappears in a couple of minutes.

**Contraindications** Actinol® Solution Plus in the following cases: It is not suitable for use in the cartilage and aseptic joint surgeries, in the middle and internal ear and in the eye (Actinol® Solution Plus contacts the aseptic cartilage, wash immediately with Ringer solution or physiological saline solution).

- If the patient is known or suspected to be hypersensitive to any of the ingredients,
- On central nervous system or meningis,
- Along with anionic surfactants, cleansing soaps, creams, oils, enzymes, etc. These substances should be removed fully from the wound surface before use.
- For peritoneal lavage and washing,
- It should not be used in the first four months of pregnancy. Depending on the risk-benefit ratio, it should be used later in pregnancy should be evaluated according to the doctor's recommendation.

**Warnings and Precautions** Read the instructions carefully before use. Only for external application onto skin. Do not use for infusion or injection purposes. Do not swallow! Keep out of reach of children. Do not use if the sealing under the cap is torn or broken. Close the bottle immediately after use to avoid any contamination. The rim of the bottle should be protected from direct contact to avoid contamination while using. Bottles, which directly contact the wound or are contaminated in some other ways should be disposed. Keep only in original packaging contact from sunlight. Dispose according to local regulations.

**For newborns and infants:** Due to the insufficiency of clinical information, Actinol® Solution Plus should be used only under a strict and close medical supervision on newborns and infants.

This product is a Class II Medical Device according to the 93/42/EEC and the 2007/47/EC amendments.

**Ingredients:** Poloxamer, Polyhexamethylene biguanide (PHMB, 0.1%) and excipients.

**Appearance and odor:** Clear, colorless and almost odorless solution.

**Shelf life:** Please see the expiry date. Close the cap tightly and store in a cool, dry and frost-free environment. Shelf life is 2 (two) years at room temperature. Do not store an opened bottle above 35 °C. Consume the open product within 8 (eight) weeks.

**DE MODE D'EMPLOI**

**Actinol® Solution Plus**

Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des plaies. Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des plaies à utiliser avec du matériel tel que des bandes, des pansements, des compresses et du matériel de remplissage des plaies pour les plaies aiguës, chroniques et infectées ainsi que les brûlures au 1<sup>er</sup> et 2<sup>nd</sup> degré. Actinol® Solution Plus nettoie mécaniquement les plaies. Elle contient des agents tensioactifs qui permettent un nettoyage des plaies pratique et indolore sans pour le traitement afin de réduire la tension de surface. Actinol® Solution Plus contribue au processus de cicatrisation des plaies en apportant aux zones traitées un effet nettoyant et hydratant très positif. Actinol® Solution Plus detegre le ferre mecanicamente. L'ensioactivo presenti nella sua composizione permettono la detersione comoda e indolore necessaria prima del trattamento della ferita. Actinol® Solution Plus facilita el proceso de curación de la herida al garantizar un efecto de limpieza y humectación muy positivo en las áreas de aplicación. Actinol® Solution Plus puede usarse también para la limpieza y el ablandado antisépticos de los materiales del apósito. Actinol® Solution Plus también puede ser utilizado para la limpieza antiséptica y suavización de los materiales de curativo. Ligaduras y pensos secos y colados a ferida podem ser humedecidos com o Actinol® Solution Plus antes da remoção, de modo que os microorganismos nes estabelecidos possam ser eliminados e eles possam ser removidos com facilidade sem provocarem traumas secundários na ferida. O efeito antimicrobiano do Actinol® Solution Plus oferece uma solução ideal para evitar a formação de biofilmes em ligaduras e pensos. Actinol® Solution Plus não impede a granulação ou epitelização. Não irrita nem causa dor. Não provoca sensibilização e pode essere utilizzato a sicurezza per un lungo periodo di tempo. La polissanide presente nella sua composizione è stata clinicamente testata milioni di volte, è dermatologicamente innocua e considerata agente di prima scelta per il trattamento delle ferite. Per un sano processo di guarigione, la detersione e il trattamento della ferita devono essere effettuati a intervalli regolari. "Recomendación de consenso de la Asociación Alemana para la Curación y el Tratamiento de Heridas (DgWfW) en 2004 y 2009.

**Indicazioni**

- Plaies aiguës infectées ou non (p. ex. plaies traumatiques dues à une coupure, déchirure, morsure, écorchure, éraecement, morsure, piqûre, etc., ou plaies chirurgicales),
- Plaies chroniques infectées ou non (p. ex. ulcères diabétiques, ulcères veineux, escarres, etc.),
- Plaies thermiques ou chimiques infectées ou non (p. ex. brûlure au 1<sup>er</sup> et 2<sup>nd</sup> degré, brûlure chimique, etc.),
- Plaies causées par un courant électrique,
- Plaies d'irradiation,
- Points d'entrée de cathéters urologiques,
- Entretien de la peau péri-stomale, des fistules et des abcès,
- Convient au nettoyage et à l'entretien de la surface de la plaie avant de poser un pansement.

Actinol® Solution Plus should be used for wound surface cleaning and irrigation before any treatment. Actinol® Solution Plus can be applied in combination with Actinol® Gel Plus. The wound should be cleaned with Actinol® Gel Plus to remove any contaminants and deposits. Bandages, dressings, pads etc. soaked in Actinol® Solution Plus can be used to clean wounds.

Actinol® Solution Plus can also be used for antiseptic cleansing and softening of encrusted dressing materials that are dried and adhered to the wound surface and difficult to remove. Actinol® Solution Plus softens the encrusted bandage and dressing, while eliminating the pathogenic microorganisms that have settled on them and prevents the wound from being infected.

Actinol® Solution Plus can be applied directly onto the wound as well as onto the bandage and gauzes. Materials

such as bandage, gauze, wiping clothes, etc. should not be used again. Actinol® Solution Plus can be heated to body temperature prior to use.

Usage with dressings and bandages Thoroughly wet dressings and bandages adhered to the wound surface with Actinol® Solution Plus, wait ca. 5-10 min. For softening and remove them carefully from wound. In order to maintain a moist wound climate, the dressing can be changed daily, if necessary, several times a day. Actinol® Solution Plus is compatible with all modern wound dressings.

Catheter care Possible infections can be avoided by regular cleaning catheter inlet ports, flexible connectors and its environment by Actinol® Solution Plus. Spray Actinol® Solution Plus on the area from a short distance and wait ca. 1-5 min. The ingredients of Actinol® Solution Plus are particularly mucous membrane-friendly, cleanse catheter and PEG material without damaging it. As with wound care, encrusted sticking plasters can be removed easily after wetting with Actinol® Solution Plus.

Side Effects Actinol® Solution Plus contains polyhexanide. Even though it is not irritating, it can cause allergic reactions in the bands and the patient's hands. Actinol® Solution Plus is reported that polyhexanide may cause an anaphylactic shock in rare cases (less than 1 out of 10,000). When allergic skin testing is recommended should not use. Patients hypersensitive to polyhexanide should not use the product. The biocompatibility index of Actinol® Solution Plus is found to be >1 and has a high tissue compatibility. Actinol® Solution Plus may cause allergic reactions such as itching (urticaria) and rash (eczema). In very rare cases, a mild burning sensation may occur after application of Actinol® Solution Plus, however this sensation disappears in a couple of minutes.

**Contraindications** Actinol® Solution Plus in the following cases: It is not suitable for use in the cartilage and aseptic joint surgeries, in the middle and internal ear and in the eye (Actinol® Solution Plus contacts the aseptic cartilage, wash immediately with Ringer solution or physiological saline solution).

- If the patient is known or suspected to be hypersensitive to any of the ingredients,
- On central nervous system or meningis,
- Along with anionic surfactants, cleansing soaps, creams, oils, enzymes, etc. These substances should be removed fully from the wound surface before use.
- For peritoneal lavage and washing,
- It should not be used in the first four months of pregnancy. Depending on the risk-benefit ratio, it should be used later in pregnancy should be evaluated according to the doctor's recommendation.

**Warnings and Precautions** Read the instructions carefully before use. Only for external application onto skin. Do not use for infusion or injection purposes. Do not swallow! Keep out of reach of children. Do not use if the sealing under the cap is torn or broken. Close the bottle immediately after use to avoid any contamination. The rim of the bottle should be protected from direct contact to avoid contamination while using. Bottles, which directly contact the wound or are contaminated in some other ways should be disposed. Keep only in original packaging contact from sunlight. Dispose according to local regulations.

**For newborns and infants:** Due to the insufficiency of clinical information, Actinol® Solution Plus should be used only under a strict and close medical supervision on newborns and infants.

This product is a Class II Medical Device according to the 93/42/EEC and the 2007/47/EC amendments.

**Ingredients:** Poloxamer, Polyhexamethylene biguanide (PHMB, 0.1%) and excipients.

**Appearance and odor:** Clear, colorless and almost odorless solution.

**Shelf life:** Please see the expiry date. Close the cap tightly and store in a cool, dry and frost-free environment. Shelf life is 2 (two) years at room temperature. Do not store an opened bottle above 35 °C. Consume the open product within 8 (eight) weeks.

**DE MODE D'EMPLOI**

**Actinol® Solution Plus**

Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des plaies. Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des plaies à utiliser avec du matériel tel que des bandes, des pansements, des compresses et du matériel de remplissage des plaies pour les plaies aiguës, chroniques et infectées ainsi que les brûlures au 1<sup>er</sup> et 2<sup>nd</sup> degré. Actinol® Solution Plus nettoie mécaniquement les plaies. Elle contient des agents tensioactifs qui permettent un nettoyage des plaies pratique et indolore sans pour le traitement afin de réduire la tension de surface. Actinol® Solution Plus contribue au processus de cicatrisation des plaies en apportant aux zones traitées un effet nettoyant et hydratant très positif. Actinol® Solution Plus detegre le ferre mecanicamente. L'ensioactivo presenti nella sua composizione permettono la detersione comoda e indolore necessaria prima del trattamento della ferita. Actinol® Solution Plus facilita el proceso de curación de la herida al garantizar un efecto de limpieza y humectación muy positivo en las áreas de aplicación. Actinol® Solution Plus puede usarse también para la limpieza y el ablandado antisépticos de los materiales del apósito. Actinol® Solution Plus también puede ser utilizado para la limpieza antiséptica y suavización de los materiales de curativo. Ligaduras y pensos secos y colados a ferida podem ser humedecidos com o Actinol® Solution Plus antes da remoção, de modo que os microorganismos nes estabelecidos possam ser eliminados e eles possam ser removidos com facilidade sem provocarem traumas secundários na ferida. O efeito antimicrobiano do Actinol® Solution Plus oferece uma solução ideal para evitar a formação de biofilmes em ligaduras e pensos. Actinol® Solution Plus não impede a granulação ou epitelização. Não irrita nem causa dor. Não provoca sensibilização e pode essere utilizado a sicurezza per un lungo periodo di tempo. La polissanide presente nella sua composizione è stata clinicamente testata milioni di volte, è dermatologicamente innocua e considerata agente di prima scelta per il trattamento delle ferite. Per un sano processo di guarigione, la detersione e il trattamento della ferita devono essere effettuati a intervalli regolari. "Recomendación de consenso de la Asociación Alemana para la Curación y el Tratamiento de Heridas (DgWfW) en 2004 y 2009.

**Indicazioni**

- Plaies aiguës infectées ou non (p. ex. plaies traumatiques dues à une coupure, déchirure, morsure, écorchure, éraecement, morsure, piqûre, etc., ou plaies chirurgicales),
- Plaies chroniques infectées ou non (p. ex. ulcères diabétiques, ulcères veineux, escarres, etc.),
- Plaies thermiques ou chimiques infectées ou non (p. ex. brûlure au 1<sup>er</sup> et 2<sup>nd</sup> degré, brûlure chimique, etc.),
- Plaies causées par un courant électrique,
- Plaies d'irradiation,
- Points d'entrée de cathéters urologiques,
- Entretien de la peau péri-stomale, des fistules et des abcès,
- Convient au nettoyage et à l'entretien de la surface de la plaie avant de poser un pansement.

Actinol® Solution Plus should be used for wound surface cleaning and irrigation before any treatment. Actinol® Solution Plus can be applied in combination with Actinol® Gel Plus. The wound should be cleaned with Actinol® Gel Plus to remove any contaminants and deposits. Bandages, dressings, pads etc. soaked in Actinol® Solution Plus can be used to clean wounds.

Actinol® Solution Plus can also be used for antiseptic cleansing and softening of encrusted dressing materials that are dried and adhered to the wound surface and difficult to remove. Actinol® Solution Plus softens the encrusted bandage and dressing, while eliminating the pathogenic microorganisms that have settled on them and prevents the wound from being infected.

Actinol® Solution Plus can be applied directly onto the wound as well as onto the bandage and gauzes. Materials

such as bandage, gauze, wiping clothes, etc. should not be used again. Actinol® Solution Plus can be heated to body temperature prior to use.

Usage with dressings and bandages Thoroughly wet dressings and bandages adhered to the wound surface with Actinol® Solution Plus, wait ca. 5-10 min. For softening and remove them carefully from wound. In order to maintain a moist wound climate, the dressing can be changed daily, if necessary, several times a day. Actinol® Solution Plus is compatible with all modern wound dressings.

Catheter care Possible infections can be avoided by regular cleaning catheter inlet ports, flexible connectors and its environment by Actinol® Solution Plus. Spray Actinol® Solution Plus on the area from a short distance and wait ca. 1-5 min. The ingredients of Actinol® Solution Plus are particularly mucous membrane-friendly, cleanse catheter and PEG material without damaging it. As with wound care, encrusted sticking plasters can be removed easily after wetting with Actinol® Solution Plus.

Side Effects Actinol® Solution Plus contains polyhexanide. Even though it is not irritating, it can cause allergic reactions in the bands and the patient's hands. Actinol® Solution Plus is reported that polyhexanide may cause an anaphylactic shock in rare cases (less than 1 out of 10,000). When allergic skin testing is recommended should not use. Patients hypersensitive to polyhexanide should not use the product. The biocompatibility index of Actinol® Solution Plus is found to be >1 and has a high tissue compatibility. Actinol® Solution Plus may cause allergic reactions such as itching (urticaria) and rash (eczema). In very rare cases, a mild burning sensation may occur after application of Actinol® Solution Plus, however this sensation disappears in a couple of minutes.

**Contraindications** Actinol® Solution Plus in the following cases: It is not suitable for use in the cartilage and aseptic joint surgeries, in the middle and internal ear and in the eye (Actinol® Solution Plus contacts the aseptic cartilage, wash immediately with Ringer solution or physiological saline solution).

- If the patient is known or suspected to be hypersensitive to any of the ingredients,
- On central nervous system or meningis,
- Along with anionic surfactants, cleansing soaps, creams, oils, enzymes, etc. These substances should be removed fully from the wound surface before use.
- For peritoneal lavage and washing,
- It should not be used in the first four months of pregnancy. Depending on the risk-benefit ratio, it should be used later in pregnancy should be evaluated according to the doctor's recommendation.

**Warnings and Precautions** Read the instructions carefully before use. Only for external application onto skin. Do not use for infusion or injection purposes. Do not swallow! Keep out of reach of children. Do not use if the sealing under the cap is torn or broken. Close the bottle immediately after use to avoid any contamination. The rim of the bottle should be protected from direct contact to avoid contamination while using. Bottles, which directly contact the wound or are contaminated in some other ways should be disposed. Keep only in original packaging contact from sunlight. Dispose according to local regulations.

**For newborns and infants:** Due to the insufficiency of clinical information, Actinol® Solution Plus should be used only under a strict and close medical supervision on newborns and infants.

This product is a Class II Medical Device according to the 93/42/EEC and the 2007/47/EC amendments.

**Ingredients:** Poloxamer, Polyhexamethylene biguanide (PHMB, 0.1%) and excipients.

**Appearance and odor:** Clear, colorless and almost odorless solution.

**Shelf life:** Please see the expiry date. Close the cap tightly and store in a cool, dry and frost-free environment. Shelf life is 2 (two) years at room temperature. Do not store an opened bottle above 35 °C. Consume the open product within 8 (eight) weeks.

**DE MODE D'EMPLOI**

**Actinol® Solution Plus**

Actinol® Solution Plus est une solution de nettoyage, d'hydratation, d'humidification et de soin des pla

