

DE GEBRAUCHSANWEISUNG

Actinol® Solution Plus Lösung zur Reinigung, Spülung, Befuchtung und Pflege von Wunden
Actinol® Solution Plus ist eine Reinigungs-, Spül-, Befuchtungs- und Pflegelösung, die zusammen mit Materialien wie Bandagen, Verbänden, Pads und Wundfilmen für akute, chronische und infizierte Wunden sowie Verbrennungen 1. und 2. Grades verwendet wird.

Actinol® Solution Plus reinigt Wunden mechanisch. Oberflächentaktive 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- plus zum Wundheilungsprozess bei, Actinol® Solution Plus ist eine sehr positive Reinigungs- und Feuchtigkeitswirkung 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 darauf abgelagerten Mikroorganismen beseitigt, und sie leicht entfernen 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 Wahl¹. Für einen gesunden Wundheilungsprozess sollte in regelmäßigen Abständen eine Wundreinigung und Pflege durchgeführt werden.

Ein Konsensusempfehlung der Deutschen Gesellschaft für Wundheilung und Wundmanagement e.V. (DGfW) 2004 & 2009.

Indikationen

- Infizierte oder nicht infizierte akute Wunden (z.B. traumatische Wunden, die durch Schmitze, 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 thermale oder chemische Wunden (z.B. Verbrennungen ersten und zweiten Grades, chemische Verbrennungen, usw.).
- Wunden, verursacht durch elektrischen Strom, Strahlungs wunden,
- Eingangsregionen von urologischen Kathetern.
- Pflege von peristomale Haut, Fisteln und Abszessen.

Geeignet zur Reinigung und Pflege von Wundoberflächen vor dem Anlegen von Verbänden, Einweichung und Entfernung von Verbandmaterialien, z.B. Bandagen, Verbänden, Wundauflagen und Wundfilmen, die getrocknet, kontaminiert und an der Wunde angehaftet sind.

Gebrauchsanweisung

Actinol® Solution Plus sollte vor jeder Behandlung zur Reinigung und Spülung von Wunden/oberfläche 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 verkürzten Verbandsmaterialien verwendet werden, die getrocknet und an der Wundoberfläche haften und schwer zu entfernen sind. **Actinol® Solution Plus** erreicht die verkürzten Stellen durch angedrücktes Aufbringen und dringt auf angesehnten pathogenen Mikroorganismen und verhindert eine Infektion der Wunde.

Actinol® Solution Plus kann direkt auf die Wunde sowie auf Verbänden und Gazen aufgetragen werden. Materialien wie Verbände, Gazen, Wischtücher usw. sollten nicht wiederverwendet werden. **Actinol® Solution Plus** kann

vor der Anwendung auf Körpertemperaturen erwärmt werden.

Anwendung mit Verbänden und Bandagen
Verbände und Bandagen, die auf der Wundoberfläche anhaften mit **Actinol® Solution Plus** gründlich benetzen, ca. 5-10 Min. einweichen lassen und anschließend vorsichtig von der Wunde entfernen. Um ein Feucht- und Wundmilieu für akute, chronische und infizierte Wunden sowie Verbrennungen 1. und 2. Grades verwendet wird.

Katheterpflege
Mögliche Infektionen können durch regelmäßige Reinigung der Katheterintestitionen, flexiblen Konnektoren und der Umgebung mit **Actinol® Solution Plus** vermieden werden. **Actinol® Solution Plus** aus kurzer Entfernung auf die Fläche sprühen und ca. 1-5 Min warten. Die Inhaltsstoffe von **Actinol® Solution Plus** sind besonders schleimhautverträglich, reinigen Katheter- und PEG-Material, ohne es zu beschädigen. Wie bei der Wundversorgung können verkürzte Heftflaster nach kurzem Benetzen mit **Actinol® Solution Plus** leicht entfernen.

Nebenwirkungen
Actinol® Solution Plus enthält Polyhexanid. Obwohl es keine Vorkommnisse in Bezug auf **Actinol® Solution Plus** gemeldet wurden, wurde berichtet, dass Polyhexanid in seltenen Fällen (weniger als 1 von 10.000) einen anaphylaktoischen Schock verursachen kann. Bei Bedarf wird vor der Anwendung ein allergischer Hauttest empfohlen. Patienten mit Überempfindlichkeit gegen Polyhexanid sollten das Produkt nicht anwenden. Liegt der Biokompatibilitätsindex von **Actinol® Solution Plus** bei >1 und weist eine hohe Gewebeverträglichkeit auf.

Actinol® Solution Plus kann allergische Reaktionen wie Juckreiz (Urtikaria) und Hautausschlag (Ekzem) hervorrufen. In sehr seltenen Fällen kann durch die Anwendung von **Actinol® Solution Plus** ein leichtes Brennen auftreten, das jedoch nach wenigen Minuten verschwindet.

Kontraindikationen
Actinol® Solution Plus sollte in den folgenden Fällen nicht verwendet werden:

- Es ist nicht geeignet für die Anwendung bei hyalinen Knorpel- und asthetische Gelenkoperationen, im Mittel- und Innenohr und im Auge (falls **Actinol® Solution Plus** Kontakt mit dem augenärztlichen Knorpel hat, sofort mit Ringer-Lösung oder physiologischer Kochsalzlösung spülen).

- Wenn bekannt ist oder vermutet wird, dass der Patient gegen einen der Bestandteile überempfindlich ist.
- Am Zentralnervensystem und an der Hirnhaut.
- Zusammen mit anionischen Tensiden, Reinigungsseifen, Cremes, Ölen, Enzymen usw. Diese Substanzen sollten vor der Anwendung vollständig von der Wundoberfläche entfernt werden.
- Für Peritonealspülungen und Waschungen.
- Es sollte in den ersten vier Monaten der Schwangerschaft nicht angewendet werden.

Abhängig von der Risiko-Nutzen-Bewertung sollte eine Anwendung des **Actinol® Gel Plus** entsprechend der Empfehlung des Arztes bewertet werden.

Warnungen und Sicherheitschweise
Lesen Sie die Anweisungen vor der Verwendung sorgfältig durch. Nur zur äußerlichen Anwendung auf der Haut. Nicht für Infusions- oder Injektionszwecke verwenden. Nicht schlucken! Außerhalb der Reichweite von Kindern aufbewahren. Nicht verwenden, wenn die Verpackung unter dem Deckel gerissen oder beschädigt ist. Verschließen Sie die Flasche sofort nach Gebrauch, um eine Kontamination zu vermeiden. Die Flaschenöffnung sollte vor direktem Kontakt geschützt werden, um eine Kontamination während der Anwendung zu vermeiden. Flaschen, die direkt mit der Wunde in Kontakt kommen oder auf andere Weise verunreinigt sind, sollten entsorgt werden. Nur in der Originalverpackung aufbewahren. Vor direktem Sonnenlicht schützen. Gemäß den örtlichen Vorschriften entsorgen. Entsorgung gemäß den örtlichen Vorgaben.

Für Neugeborene und Säuglinge: Auftragen Sie zusätzliches klinischer Information sollte **Actinol® Solution Plus** für Neugeborenen und Säuglingen nur unter strenger und enger ärztlicher Überwachung angewendet werden. Dieses Produkt ist ein Medizinprodukt der Klasse III gemäß Regel 13 von Anhang IX der Medizinprodukte Richtlinie

93/42/EWG und den Änderungen 2007/47/EG.
Zusammensetzung: Poloxamer, Polyhexamethylenbiguanid (PHMB, 0,1%) und Hilfsstoffe.
Aussehen und Geruch: Klar, farblos und fast geruchlos Lösung.

Haltbarkeit: Bitte beachten Sie das Verfallsdatum. Verschließen Sie die Kappe dicht und lagern Sie in einer kühlen, trockenen und frostfreien Umgebung auf. Die Haltbarkeit beträgt 2 (zwei) Jahre bei Raumtemperatur. Angerohene 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 1st and 2nd 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 that are 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 it 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 agent¹. For a healthy wound recovery, prompt cleaning and care should be followed in regular intervals.

¹Consensus recommendation of the German Society for Wound Healing and Wound Management e.V. (DGfW) 2004 & 2009.

Indications

- Infected or uninfected acute wounds (e.g. traumatic wounds that occur as the result of cuts, tears, excoriation, crushing, being bitten, being stung, etc.).

- Infected or uninfected chronic wounds (e.g. diabetic ulcers, venous ulcers, decubitus (pressure sore), etc.).
- Infected or uninfected thermal or chemical wounds (e.g. 1st and 2nd 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. Suitable for antiseptic cleansing, softening and removal of dressing materials, i.e. bandages, dressings, pads and wound fillers that are dried, contaminated and adhered to the wound.

Instructions for Use
Actinol® Solution Plus should be used to 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® Solution 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 bandages, 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 has no irritant effect on intact skin, there are isolated cases of allergic reactions to polyhexanide when used as an anaphylactic shock in rare cases (less than 1 out of 10,000). When allergic skin testing is recommended before 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 the 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 should not be used in the following cases:

- It is not suitable for use in cartilage surgery and aseptic joint surgeries, in the middle and internal ear and in the eye (If **Actinol® Solution Plus** contacts the aseptic catheter, 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 meninx,
- 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 evaluation, it is safe 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 sealang under the cap is torn or broken. Use 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 and do not return. 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 rule 13 of Annex IX of the Medical Device Directive 93/42/EEC and the 2007/47/EC amendments.

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Appearance and odor: Clear, colorless and almost odourless solution.

Shelf life: Please see the expiry date. Close the cap tightly and store in a cool, dry and dark 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.

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riscaldata alla temperatura corporea prima dell'uso. **Usa con medicazioni e bende**

Bagnare completamente le bende e le medicazioni aderenti alla superficie della ferita con **Actinol® Solution Plus**, attendere ca. 5-10 min per ammorbidire e rimuovere accuratamente dalla ferita. Al fine di mantenere un clima umido sulla ferita, la medicazione può essere cambiata quotidianamente e, se necessario, più volte al giorno.

Actinol® Solution Plus è compatibile con tutte le comuni medicazioni.
Cura del catetere
Per evitare infezioni ridurre regolarmente gli ingressi del catetere, i connettori flessibili e la cina crosante con **Actinol® Solution Plus**. Spruzzare **Actinol® Solution Plus** sulla zona da trattare da una breve distanza e attendere ca. 1-5 min. I componenti di **Actinol® Solution Plus** sono particolarmente delicati sulle mucose, detergono la detersione comoda e indolore necessaria prima del trattamento della ferita, riducendo la tensione superficiale.

Actinol® Solution Plus contribuisce al processo di guarigione delle ferite garantendo un'azione detergente e idratante molto efficace sulle zone di applicazione. **Actinol® Solution Plus** può essere utilizzato anche per la detersione antistatica e per ammorbidire i materiali 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.

Effetti collaterali
Actinol® Solution Plus contiene poliossianide. Anche se non ha un effetto irritante sulla pelle, ci sono casi isolati di reazioni allergiche a poliossianide quando usato come un anafilattico shock in casi rari (meno di 1 su 10.000). Quando necessario, si consiglia di effettuare prove allergiche cutanee prima dell'uso. I pazienti ipersensibili alla poliossianide non devono utilizzare il prodotto. L'azione antimicrobica di **Actinol® Solution Plus** rappresenta la soluzione ideale per prevenire la formazione di biofilm su bende e medicazioni.

Actinol® Solution Plus non inibisce la granulazione né l'epitelizzazione. Non irrita né causa dolore. Non provoca sensibilizzazione e può essere utilizzato in sicurezza per un lungo periodo di tempo. La poliossianide presente nella sua composizione è stata clinicamente testata milioni di volte, e dermatologicamente sicura 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.

Contraindicazioni
Non utilizzare **Actinol® Solution Plus** nei seguenti casi:

- Non è adeguato per la cura di lesioni di cartilagine ialina o articolazione asettica, in un occhio o interno, ni e/o in olo (Se **Actinol® Solution Plus** entra in contatto con il cartilagine asettico, se deve lavar immediatamente con soluzione Ringer o soluzione salina fisiologica).

- Se è noto o si sospetta che il paziente sia ipersensibile a una qualsiasi dei componenti;
- Unitamente a tensioattivi anionici, saponi detergenativi, creme, oli, enzimi ecc. Queste sostanze devono essere completamente rimosse dalla superficie della ferita prima dell'uso;
- Per il lavaggio peritoneale;
- Non deve essere utilizzata nei primi quattro mesi di gravidanza. In base alla valutazione del rapporto rischio-beneficio, il suo utilizzo in una fase successiva della gravidanza deve essere valutato secondo le raccomandazioni del medico.

Avvertenze e precauzioni

Leggere attentamente le istruzioni prima dell'uso. Solo per applicazione esterna sulla cute. Non utilizzare per infusioni o iniezioni. Non ingerire! Tene fuori dalla portata dei bambini. Non utilizzare se la sigillatura sotto il tappo è strappata o rotta. Chiudere immediatamente il flacone dopo l'uso. Non utilizzare un prodotto che ha subito rotto il flacone deve essere protetto dal contatto diretto per evitare la contaminazione durante l'uso. I flaconi che vengono direttamente a contatto con la ferita o che sono contaminati in altro modo devono essere smaltiti. Conservare solo nella confezione originale. Proteggere dalla luce del sole. Smaltire senza contaminare e depositi. Per detergere le ferite si possono utilizzare bende, medicazioni, compresse ecc. Imbevute di **Actinol® Solution Plus** deve essere utilizzata sotto stretto e

