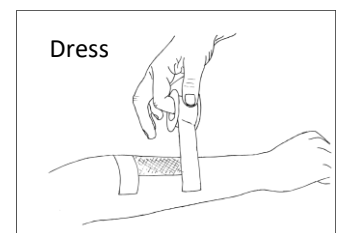
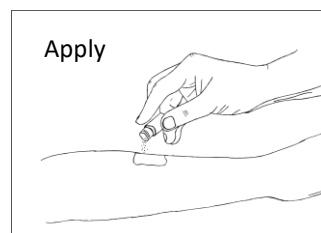
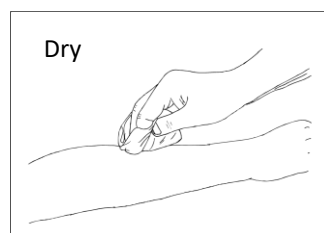
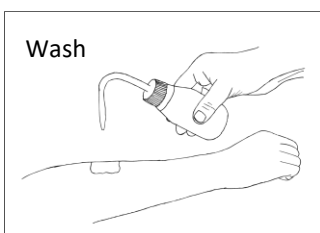


Treatment for wounds

| | | |
|--|--|---|
| <p>CE 0537</p> | DO NOT: <ul style="list-style-type: none"> • Use if the bottle is damaged. • Use if the shelf life has expired (see bottle). • Expose the bottle to a direct heat source. • Combine Amicapsil with any other products or therapies which may exert an effect directly on the wound. | DO: <ul style="list-style-type: none"> ✓ Keep Amicapsil out of the reach and sight of children. ✓ Store refrigerated (2°C to 10°C). ✓ Use within 15 days of first opening the bottle. ✓ Close the bottle after each use and place it in the fridge. ✓ Recycle both the bottle (HDPE) and cardboard box – according to local regulations. Non-hazardous waste. |
| <p>Manufacturer: Willingsford Ltd., NFEC, Rushington Business Park, Chapel Lane, Southampton, SO40 9LA, UK. contact@willingsford.com</p> | | |

INDICATED FOR:

- | | | | |
|------------------------|-------------------|-------------------|--|
| ✓ Diabetic foot ulcers | ✓ Chronic wounds | ✓ Surgical wounds | ✓ Boils, Furuncles, Carbuncles |
| ✓ Venous leg ulcers | ✓ Open abscesses | ✓ Burns | ✓ Open pimples, spots, zits. |
| ✓ Pressure ulcers | ✓ Physical trauma | ✓ Infected wounds | ✓ Erupted papules, pustules, cysts, whiteheads |

GUIDANCE FOR PREPARATION, APPLICATION, USE AND AFTER-USE

PROCEDURE

Please read these instructions in full before applying Amicapsil.

✚ Indicates that the specific product can be obtained from a pharmacy.

✖ Indicates that the specific ingredient or product is to be avoided, e.g. in case it is suggested to you at the pharmacy.

1. Assess the wound

If you are in doubt, or the wound is very deep, large and/or contains exposed bone, tendon, access to cavities or ruptured sutures, Amicapsil may prove effective, but the wound should first be assessed by a healthcare professional.

Do not apply Amicapsil but consult a doctor if you suspect any other complication deeper in the wound such as:

- The reddened area surrounding the wound is extensive or increasing in size.
- There may be a broken or chipped bone or a foreign body, for example a piece of grit or small thorn.
- There could be a cyst, abscess or tumour.

Amicapsil is not effective on completely dry surfaces.

2. Create a clean environment

Wash your hands. Place an absorbent pad under the wounded area. Put on clean single use gloves.

Always change gloves after cleaning the wound, before applying Amicapsil and/or a clean dressing.

3. Wound preparation

Remove dirt, pus, dead tissue, slough, any very old scabs or other evidently inappropriate material.

4. Clean the wound

Wash the wound thoroughly under the tap or in the shower using a hand-held shower head. Otherwise, use a wash-bottle (or alternatively a large syringe) to allow a good cleaning pressure without harming the wound bed. Tap water is preferable, but a saline solution ✚, may be used to wash the

wound instead. A wash bottle ✚ can be easily obtained from Willingsford Ltd., a pharmacy or via the internet.

If the wound is full of pus and dead tissue that you cannot remove by washing as above; or if you suspect strong contamination of the wound has occurred, e.g. a bite, a 3% hydrogen peroxide (H₂O₂) solution ✚ can be used. Apply, allow for froth creation and wash off with water. Do not leave on for longer than 20-30 seconds, and then wash off with water. Repeat this procedure a few times, and cease application once no froth is created, indicating a clean wound. H₂O₂ should not be used in very deep or large wounds as there is a risk of gas embolism.

Avoid the use of all antimicrobials and antiseptics such as chlorhexidine, polihexanide, iodine, PHMB octenidine, cetrimide or polyaminopropyl biguanide ✖.

5. Dry the wound gently

Using a dry lint-free swab (gauze pad) ✚ carefully dab the wound dry.

6. Apply the primary dressing - Amicapsil
On shallow wounds:

Sprinkle Amicapsil in an even layer 1-3 mm thick, directly onto the entire wound surface, including beneath loose flaps of skin and any undermined areas.

Cover the wound edges well, extending to an area 2-5mm from the wound edge, onto the surface of the unbroken skin surrounding the wound opening. Very gently rub Amicapsil into any reddened and/or inflamed skin in the vicinity of the wound. If necessary, gently use a dry gauze swab or your gloved finger to ensure all areas are covered with Amicapsil, including the underside of any affected flaps of skin, by dabbing upwards.

If the wound is on a vertical surface, e.g. on the lower leg, apply a 1-3mm thick layer of Amicapsil the size of the wound, plus an extra 5mm perimeter directly onto a dressing (see section 7). Place it directly over the wound and fix it there using sticking plaster tape.

On deep wounds or cavity wounds:

Sprinkle Amicapsil into the cavity and use a gauze swab or your gloved finger to even it out and cover the entire wound surface – the area that is exposed to the air and in any way accessible from the opening in the skin. The layer should be 1-3 mm thick and will usually be the amount that sticks to the wound surfaces. The areas to cover include the visible area, all sides of the wound, all crevices, between flaps, beneath loose flaps of skin and any undermined areas and all surfaces lining any tunnelling. Ensure Amicapsil reaches the bottom of any tunnel. Cover the wound edges well, extending to an area 2-5mm from the wound edge, onto the surface of the unbroken skin surrounding the wound opening.

7. Apply a secondary dressing

To keep the Amicapsil layer in place on the wound, cover it with a very light, dry and highly permeable dressing. This allows the wound to 'breathe' - access to air promotes an environment favourable to healing and permits evaporation.

Alternatively, see the section "Wounds in difficult-to-dress areas" below.

We recommend 4 options – of which option A and B are better and should be preferred in difficult wounds and patients with immune deficiency:

- A. 4-ply thin lint-free 100% cotton gauze swab (this is coded "BP Type 13 Light") +, e.g. "Premier 1660 Cotton Gauze Swabs" secured with sticking plaster tape. Apply the pad directly on top of the Amicapsil after making extra sure that the entire area of broken skin is well covered with Amicapsil and that Amicapsil has been very gently rubbed into any red non-broken skin.
- B. 2-ply thin lint-free 100% cotton gauze swab +, e.g. "Premier 1660 Cotton Gauze Swabs (BP Type 13 Light)" fastened with open netted gauze roll or tubular net (see Section 8 Securing the dressing).

As long as Amicapsil is in between the 100% gauze and the wound surface, the gauze will not stick to the wound surface. If a gauze is lightly stuck at the time of removal, simply soak it with a bit of clean water for a little while until it comes loose easily without use of force.

- C. Contact layer dressing (see this section below) covered with 1-ply of gauze and secured with sticking plaster tape.
- D. Contact layer dressing fastened with open netted gauze roll, tubular gauze or surgical stockinette (see section 8).

The contact layer dressing must be paper thin, dry, non-impregnated, non-adhesive and of a very open mesh that makes it highly permeable. An examples of a suitable contact layer dressing is N-A from Systagenix +. Take care when choosing a contact layer dressing. Many such dressings are impregnated ✘ with substances such as paraffin, lipido-colloids, triglycerides (fatty acids), petrolatum, ointment, honey, iodine, silver etc. **THESE MUST BE AVOIDED** because Amicapsil cannot work if used in combination with other products that exert any effect directly on the wound. Contact layer dressings that are auto-adhesive **SHOULD BE AVOIDED** due to risk of allergy, e.g. Mepitel and Adaptic Touch ✘. Any allergic/sensitive reaction to the secondary dressing interferes with and stops the healing process initiated by Amicapsil.

The sole purpose of the contact layer dressing is to hold the Amicapsil in place on the wound and wound edges.

If the secondary dressing or the fastening tape cause an allergic reaction or sensitivity, e.g. seen as redness and/or dryness next to the wound edges, itchiness in the surrounding area, dryness and/or tiny wounds around the dressing-edges, **DO NOT USE** it, as it stops the healing process. Instead, use option A or B from

this section combined with option B or D from the section below on using net for fixation and no tape.

8. Securing the Dressing

Options A & C:

Fasten the secondary dressing using sticking plaster tape. The tape should not pass over the wound area as that may block evaporation and access to air; it should run only over areas with healthy skin underneath (e.g. along the borders of the dressing). Examples of suitable tapes are Omnifix and Hypafix + which aim to ensure firm adherence to the skin, or alternatively Leukosilk and Urgofix + which target reduced risk of sensitivity, as well as pain and damage to the skin when removed.

Options B & D:

Depending on the location of the wound, e.g. feet, ankles or legs, and on any vascular issues in the area, it can be preferable to fasten the gauze pad (Option B) or the contact layer dressing (Option D) with a layer of open weave tubular net, e.g. Surgifix, Tg-Fix or Stülpa-fix, +. This will hold the Amicapsil and the secondary dressing in place without the need to stick anything to the skin. For other locations, cover lightly using very open-weave gauze roll and fasten this with tape to the gauze itself. The net/gauze roll is **NOT** intended to apply pressure to the wound or to the surrounding area. Its only aim is to fasten the secondary dressing pad – see Section 7.

If the skin is allergic to adhesives, e.g. get red, dry or blistered, or is so fragile that application of any adhesive to keep the dressing in place is likely to break the skin upon removal, use the gauze or tubular net option to fasten the pad. Alternatively, leave the Amicapsil layer uncovered. See the section on Difficult-to-Dress Areas.

Once dressed, remember:

- Avoid applying pressure to the wound surface, e.g. by resting your hand on the wounded area. Do not, for example, tighten shoes or boots over a foot wound.
- Avoid blocking the access of air, e.g. by placing a wound located on the back of a leg on top of a pillow.
- Minimise the time Amicapsil is outside the refrigerator.

WOUNDS IN DIFFICULT-TO-DRESS AREAS

If needed, Amicapsil can be used on a wound without a dressing or bandage covering it. Follow the standard preparation and cleaning procedures as described above, then dab as much Amicapsil onto the wound as will stick. Because there is no covering, Amicapsil may need to be reapplied more frequently as the Amicapsil layer will be at risk of being worn off.

FREQUENCY OF APPLICATION

Best results will be obtained by applying Amicapsil once every day until the amount of cloudy liquid secreted by the wound is very low and the wound no longer looks dirty or caked on the surface when the dressing is removed.

In new wounds in healthy individuals, this will on average be between 1 and 5 days.

In old wounds in individuals with an underlying medical condition, the number of applications will depend on the individual conditions. In wound incapable of closure, Amicapsil is used to keep the wound or ulcer free of infection.

If a dirty, caked and/or very wet appearance reappears at a later stage in the healing process, use Amicapsil as before until the wound is clean. One application is usually sufficient.

As a general rule, the better the wound is washed with tap-water between dressing changes, the smaller number of applications will be required.

Spinal Cord Injured Patients (SCI)

In SCI-patients, Amicapsil should preferably be applied daily until wound closure as this patient group suffers from generalised immune deficiency syndrome.

PROFUSELY DISCHARGING WOUNDS

If the wound is oozing uncontrollably, the most effective way to use Amicapsil is to follow the standard preparation, application and dressing procedures described above. When the dressing is completely *soaked*, change the Amicapsil and secondary dressing. This may have to be done 2 to 3 times, with increasing intervals between changes, for the first 24 hours of use, for example after 4, 8 and then 12 hours.

When the Amicapsil no longer has a soaked appearance, within 8 to 12 hours, continue the use of Amicapsil as described under Frequency of Application.

DRESSING CHANGES

Follow these steps:

- i) Remove all dressings as gently as possible. Proceed slowly and cautiously without jerking or tearing.
- ii) Gently clean the wound surface as described in section 4.
- iii) If Amicapsil has been applied correctly, i.e. covering the entire wound surface and edges, the covering dressing will not stick to the newly formed cells in the wound bed. Should it seem lightly stuck, the substance adhering to the covering dressing is usually of a gel-like consistency. This contains waste from the area beneath and surrounding the wound opening. It needs to be removed from the wound – see next step.
- iv) Very gently, remove as much loose and/or foul looking material as possible. This can be done by wiping very gently e.g. with a clean swab moistened with water. Take care not to harm new tissue and newly formed cells that may be forming in the wound bed but may still not be visible to the naked eye.
- v) Wash the wound thoroughly with water, e.g. clean tap-water - applying a good cleaning pressure by the use of – preferably - a hand-held shower head or a wash-bottle, or alternatively a big syringe, to clean out the discharge and the old Amicapsil along with any loose or foul looking matter on the wound or wound edges. The water pressure allows effective cleaning of all corners and crevices. In wounds with plenty of discharge or loose matter, you can assist the cleaning under the shower by wiping the wound surface with a moist swab, but take care not to disturb any newly formed tissue in the wound bed, **OR**
- vi) If the wound *cannot* be thoroughly washed, wipe it very gently using a moistened lint free swab. In these circumstances it is preferable to leave a tiny bit of old Amicapsil in the wound to avoid disrupting any tissue that is forming. Amicapsil does not enter the body and is not harmful.
- vii) Finally, repeat the application of Amicapsil as described in sections 5, 6 and 7.

Provided new forming cells are undamaged, the better the wound is cleaned of unwanted matter, the quicker the healing will progress.

If the wound contains substantial amounts of dead tissue, pus or other matter, seek advice from a doctor.

Duration of use

Once the wound has reached a clean and infection-free state (see next paragraph), application of Amicapsil should cease as Amicapsil enables the body's own healing process to take over. Continued use of Amicapsil is no longer necessary as the healing

process will now proceed at the natural healing speed of the individual of a wound. Please see the Section "After discontinuation of Amicapsil therapy" below.

This clean stage is usually reached within 1 to 5 days of first application in wounds less than 2 months old in healthy individuals. In chronic wounds caused by an underlying condition or disease, the time to reach the clean stage will vary. A clean, infection-free wound will be red, usually with new blood supply visible as red buds, and clean, pale white tissue on top and/or in between. The edges will be whitish and the surface shiny and moist. There should be no cloudy yellow, greenish, bluish or brownish colour, no unpleasant odour and no discharge from the wound.

Take care not to mistake lymphatic fluid (a yellowish transparent odourless discharge - which turns brown and crispy when dried out on the wound surface) for pus (cloudy yellow/orange/green/brown and possibly foul-smelling). Lymphatic fluid is a healthy wound response and will quickly diminish by itself without the use of Amicapsil.

Dressed wounds - discontinuation

The healing wound will typically have a moist and healthy pink/red surface appearance and white - not grey or red - healthy looking edges. Edges should not be wet, only moist. In a shallow wound, connective tissue with new blood supply will usually be visible as red buds in the wound bed and along the edges. This is highly desirable; the wound should now be left undisturbed for healing to progress.

The wound will normally start re-building from the bottom with new connective tissue and subsequently contract from the edges. New skin formation will be visible as pale whitish isles in and on the wound bed as well as moving in from the wound edges.

These features may appear in different areas of the wound on different days. If one part of the wound is clean and covered with red buds or white isles, only apply Amicapsil to the still struggling area. If this is not possible, cover the entire wound with Amicapsil until repetition of the process clears out the infection completely.

Non-dressed wounds - discontinuation

If the Amicapsil was not covered with a dressing, the clean, infection-free wound will typically have a dry, pale red, flexible surface, white healthy edges but without a traditional scab.

Do not touch this crisp-looking, flexible wound: leave the final Amicapsil layer on the wound and avoid it getting wet. Leave the wound undisturbed. The surface will gradually change into a healed surface.

A clean, infection-free wound can also form a natural, light-brown scab that does not ooze from underneath when a bit of pressure is applied to it. Leave this scab undisturbed.

In some cases, the clean, non-dressed wound may have an appearance similar to a clean wound which had been dressed.

AFTER DISCONTINUATION OF AMICAPSIL THERAPY

When Amicapsil therapy ceases, the wound should now be left undisturbed as newly generated cells and tissue is fragile. The micro-environmental conditions that have been created in the wound now favour healing and must be conserved. Similar to the conditions on the skin itself, this microenvironment needs access to the air. Dressings subsequently used must therefore be fully permeable and allow plenty of air to reach the wound. Any adhesion to the healing wound bed must be avoided. A paper thin, atraumatic, open mesh, fully permeable contact layer dressing, e.g. N-A from Systagenix with a 1-ply gauze on top will provide these conditions +. The procedure is similar to

that used on top of the Amicapsil layer - but without the Amicapsil. Change the dressing every week until full closure. If the dressing gets wet or soiled, change it without touching or disturbing the wound. Should the wound get wet, wash, dab dry and apply a clean dressing. When showering, apply a shower proof dressing + on top of the contact layer and remove the shower proof dressing once finished.

If the application of a shower proof dressing is not possible, e.g. because the wound is located in or directly next to an area that requires regular washing, shower as usual but don't allow any shampoos, body washes, soaps or similar with any type of antibacterial or antimicrobial properties into the wound. The wound can be washed daily with tap-water but nothing else. If a soap or similar runs over the wound area, rinse with clean tap-water afterwards. Then proceed as described above in this section.

Don't apply any skin lotions, creams, moisturisers or similar to the skin within at least 10 cm of the wound opening – not even if the skin in this area has a dry and/or flaky appearance. The flakes form part of the natural healthy healing and skin-maturation processes and they will fall off in their own time when the skin underneath is ready. Interference by removing the flakes or applying moisturisers delays the healing process. After closure, allow 6-8 weeks for the area to mature and regain strength. The wounded area will continue to regenerate and reconstruct the tissue underneath the skin and the skin itself for years.

AMICAPSIL IN CONJUNCTION WITH COMPRESSION THERAPY

Compression therapy devices and compression therapy hosiery are usually not permeable and as a result will interfere with the efficiency of Amicapsil. As there is no scientific data to support the use of compression therapy e.g. in the treatment of venous leg ulcers, it is preferable that compression therapy be suspended while Amicapsil treatment is conducted.

AMICAPSIL WITH PROTECTIVE DRESSINGS

Generally, dressings which prevent air circulation to the wound are not recommended. If a protective dressing is unavoidable, the Amicapsil layer should be covered with a highly absorbent, plain dressing (e.g. Zetuvit Plus), + without any active components (e.g. silver; polihexanide, iodine etc.) ✘. Apply the protective material on top of this secondary dressing. The protective dressing can be left in place for 1-2 days. Follow the recommended procedure for the chosen type of secondary dressing. Prolonged use of Amicapsil with the described dressing types which seal off the wound from air is not recommended.

PRECAUTIONS

Amicapsil is for External Use only

Do not eat.

Keep Amicapsil out of the eyes. Should that occur, immediately wash out the eye(s) with plenty of water or mild salt solution (saline) and seek medical attention.

The components of Amicapsil have no known toxicity as used in Amicapsil. No adverse reactions or allergic reactions have been observed or are expected. Nevertheless, avoid inhalation and exposure to the eyes.

Apply minimally on exposed nerve bundles. If bundles of nerve fibres (called fascicles) are present in the wound - as soft, white, thin tube-like structures - limit the application of Amicapsil directly onto these to a very thin layer as excessive removal of moisture may cause irritation of the nerves. In case this

happens, wash off the Amicapsil with tap water and the pain will quickly subside.

OTHER INFORMATION

Amicapsil is not absorbed by the body.

Amicapsil can be removed by simple irrigation with water.

Antibiotics can be administered in conjunction with Amicapsil. Upon commencement and completion of a course of antibiotics, expect a 24-48 hours delay or setback in the wound healing process. This arises for wounds actively receiving Amicapsil, and wounds continuing the healing process after Amicapsil therapy has ended.

DO NOT combine Amicapsil with any other treatments or therapies applied directly to the wound.

These may impact the actions of Amicapsil. Examples of topical (i.e. applied on top of the wound) treatments to avoid ✘ are:

- Honey
- Silver
- Gelling agents
- Gels
- Iodine
- PHMB
- Polihexanide
- Collagen
- Octenidine
- Cetrimide
- Chlorhexidine
- Polyaminopropyl Biguanide
- Topical Negative Pressure Wound Therapy
- Topical antibiotics, both as ointment, cream, gel and as powder
- Absorbent dressings which are impermeable to air ('occlusive') e.g. alginates, foams, etc.

DO NOT use *impregnated* contact layer dressings with substances such as paraffin, lipido-colloids, triglycerides (fatty acids), petrolatum, ointment, or any of the substances listed under the bullet points above. ✘

DO NOT use any antimicrobial substances e.g. the ones listed in the bullet points above ✘ prior to the application of Amicapsil. These are toxic and will remain in the tissue for several days and prevent healing and Amicapsil from working.

2% or 3% hydrogen peroxide (H₂O₂) solution can be used briefly and as described in Section 4 "Clean the wound".

DO NOT let the wound become wet or moist.

Avoid the wound, the Amicapsil layer and the dressing getting wet or moist from the outside, e.g. when washing, or from the inside, e.g. from perspiration.

Should that occur, clean off the old Amicapsil, wash and dry the wound and apply a new layer of Amicapsil and secondary dressing – as described in sections 5, 6 and 7.

In case of excessive sweating, consider the option not to cover Amicapsil with a secondary dressing.

Store Amicapsil refrigerated

Keep Amicapsil away from direct heat sources

Avoid direct sunlight, radiators, window sills, pockets near to the body, hot cars, running engines etc.

Use within 15 days of first opening an Amicapsil bottle

Minimise bottle contamination

If an Amicapsil bottle has touched the wound, use alcohol or isopropyl alcohol to wipe it clean.

Occlusive dressings should be avoided

Amicapsil is intended for non-sterile wounds

Use only on sterile wounds after deemed appropriate by the treating physician.

Please visit www.willingsford.com