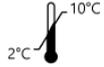


Powder for the treatment of wounds

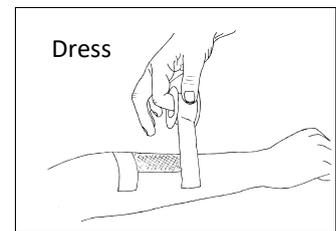
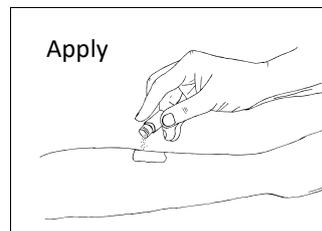
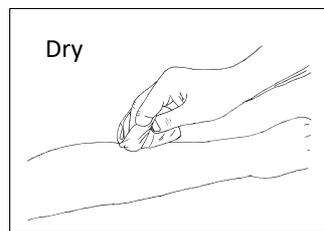
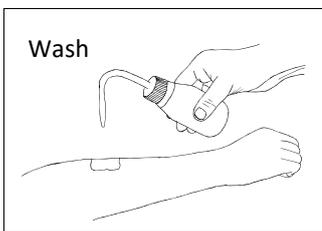
   <p>CE 0537</p>	<p><b>DO NOT:</b></p> <ul style="list-style-type: none"> <li>• Use if the bottle is damaged.</li> <li>• Use if the shelf life has expired (see bottle).</li> <li>• Expose the bottle to a direct heat source.</li> <li>• Combine Acapsil with any other products or therapies which may exert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

**INDICATED FOR:**

- ✓ Diabetic foot ulcers
- ✓ Venous leg ulcers
- ✓ Pressure ulcers
- ✓ Chronic wounds
- ✓ Open abscesses
- ✓ Physical trauma
- ✓ Surgical wounds
- ✓ Burns
- ✓ Infected wounds
- ✓ Furuncles
- ✓ Carbuncles

Acapsil is only effective on wounds and ulcers where the skin is broken.

**GUIDANCE FOR PREPARATION, APPLICATION, USE AND AFTER-USE**



**PROCEDURE**

Please read these instructions **in full** before applying Acapsil.

✚ 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, Acapsil may prove effective, but the wound should first be assessed by a healthcare professional.

Do not apply Acapsil 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.

Acapsil 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 Acapsil 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**

The preferable use of tap water and a wash-bottle (or alternatively a large syringe) will allow a good cleaning pressure without harming the wound bed. 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, a 3% hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) 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. Cease application once no froth is created, indicating a clean wound. H<sub>2</sub>O<sub>2</sub> should not be used in very deep or large wounds as there is a risk of gas embolism.

If at all possible, avoid the use of antiseptics, but if you consider it absolutely necessary, use 70% Isopropyl alcohol ✚. DO NOT USE any products containing Chlorhexidine, Polihexanide, iodine or PHMB ✖.

**5. Dry the wound gently**

Using a dry lint-free swab (gauze pad) ✚ dab the wound dry, or carefully use a warm-air dryer such as a hair dryer on a low setting - but not too close to the skin or the affected area.

**6. Apply the primary dressing - Acapsil**

Sprinkle Acapsil in an even layer 1-3 mm thick, directly onto the entire wound surface - the area that is exposed to the air and accessible from the opening in the skin. This includes the visible area, all crevices, beneath loose flaps of skin and any undermined areas, all sides of the wound and all surfaces lining any tunnelling.

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.

If necessary, gently use a swab or your gloved finger to ensure all areas are covered with Acapsil, 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 Acapsil 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.

### 7. Apply a secondary dressing

To keep the Acapsil 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.

We recommend 4 options:

- A. 4-ply lint free swab (a thin gauze pad) + secured with sticking plaster tape. Apply the pad directly on top of the Acapsil after making extra sure that the entire area of broken skin is well covered with Acapsil.
- B. 2-ply lint free swab fastened with gauze roll, tubular gauze, or surgical stockinette (see Section 8 Securing the dressing).
- C. Contact layer dressing (see this section below) covered with 2-ply gauze and secured with sticking plaster tape.
- D. Contact layer dressing fastened with gauze roll, tubular gauze or surgical stockinette.

The contact layer dressing must be paper thin, dry, non-impregnated and of an open mesh that makes it highly permeable. Examples of suitable contact layer dressings are Mepitel, Adaptic Touch, Atrauman Silicone +. 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 etc. **THESE MUST BE AVOIDED** because Acapsil cannot work if used in combination with other products that exert any effect directly on the wound.

The sole purpose of the contact layer dressing is to hold the Acapsil in place on the wound and wound edges - consequently Acapsil is applied *before* the dressing and must cover the entire wound area.

If the dressing causes a reaction, i.e. redness and/or dryness, do not use it. Instead, use option A or B.

### 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 Hypafix and Mefix + which aim to ensure firm adherence to the skin, or alternatively Leukosilk and Urgofix + which target reduced risk of sensitivity, 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 cover the gauze pad (Option B) or the contact layer dressing (Option D) with a layer of open woven tubular gauze or very thin open woven surgical stockinette+. This will hold the Acapsil 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.

If the skin is so fragile that application of any adhesive to keep the dressing in place is likely to break the skin upon removal, use only tubular gauze/stockinette. Alternatively, leave the Acapsil layer uncovered. See the section on Difficult-to-Dress Areas.

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 Acapsil is outside the refrigerator.

### WOUNDS IN DIFFICULT-TO-DRESS AREAS

If necessary, Acapsil 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 Acapsil onto the wound as will stick. Because there is no covering, Acapsil may need to be reapplied more frequently as the Acapsil layer will be at risk of being worn off.

### FREQUENCY OF APPLICATION

Best results will be obtained by applying Acapsil 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.

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

### PROFUSELY EXUDING ('WEEPING') WOUNDS

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

When the Acapsil no longer has a soaked appearance, within 8 to 12 hours, continue the use of Acapsil 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 Acapsil 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 yellow 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 with water, applying a good cleaning pressure by the use of – preferably - a wash-bottle, or alternatively a syringe, to clean out the old Acapsil along with any yellow or foul looking matter on the wound or wound edges. The water pressure allows effective cleaning of all corners and crevices 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 Acapsil in the wound to avoid disrupting any tissue that is forming. Acapsil does not enter the body and is not harmful.
- vii) Finally, repeat the application of Acapsil 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 state, application of Acapsil should cease as Acapsil enables the body's own healing process to take over. Continued use of Acapsil is no longer necessary.

This clean stage is usually reached within 1 to 5 days of first application.

A clean 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 and no discharge from the wound.

Take care not to mistake lymphatic fluid (a yellowish transparent odourless discharge) 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 Acapsil.

### 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. 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 Acapsil to the still struggling area. If this is not possible, cover the entire wound with Acapsil until repetition of the process cleans it completely.

### Non-dressed wounds - discontinuation

If the Acapsil was not covered with a dressing, the clean 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 Acapsil layer on the wound and avoid it getting wet. Leave the wound undisturbed. The surface will gradually change into a healed surface.

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

### AFTER DISCONTINUATION OF ACAPSIL THERAPY

When Acapsil therapy ceases, the wound should now be left undisturbed as newly generated cells and tissue remain 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 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 Ultra, with a 2-ply gauze on top will provide these conditions +. The procedure is similar to that used on top of the Acapsil layer - but without the Acapsil. Change the dressing every week or two 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.

## ACAPSIL IN CONJUNCTION WITH COMPRESSION THERAPY

Devices such as compression therapy hosiery are usually not permeable and as a result will interfere with the efficiency of Acapsil. Consequently it is preferable that compression therapy be suspended for a brief period, while Acapsil treatment is conducted. If that is not possible, one layer of thin, breathable, open knitted compression hosiery can be pulled over the permeable secondary dressing.

If devices which seal off the wound from the air are unavoidable in the compression therapy, the Acapsil layer should be covered with a highly absorbent, plain dressing (e.g. Zetuvit Plus; Kerrafoam; Tegaderm) or a standard absorbent, plain foam dressing (e.g. Allevyn), **+** *without* any active components (e.g. silver; PHMB) **✗**. The compression device can be used on top of this secondary dressing.

Acapsil has not been tested in conjunction with compression pumps.

## ACAPSIL WITH PROTECTIVE DRESSINGS

Generally, dressings which prevent air circulation to the wound are not recommended. If a protective dressing is necessary, dress as described in the section 'Acapsil in Conjunction with Compression Therapy' and apply the protective material. The protective dressing can be left in place for 1-2 days. Follow the recommended procedure for the chosen type of secondary dressing.

## PRECAUTIONS

### Acapsil is For External Use Only

#### Do not eat.

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

The components of Acapsil have no known toxicity as used in Acapsil. 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 Acapsil 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 Acapsil with tap water and the pain will quickly subside.

## OTHER INFORMATION

Acapsil is not absorbed by the body.

Acapsil can be removed by simple irrigation with water.

Antibiotics can be administered in conjunction with Acapsil. 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 Acapsil, and wounds continuing the healing process after Acapsil therapy has ended.

### **DO NOT combine Acapsil with any other treatments or therapies applied directly to the wound.**

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

- Honey
- Silver
- Collagen
- Gelling agents
- Iodine
- PHMB
- Gels
- Polihexanide
- Topical Negative Pressure
- 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, silver, iodine, honey etc. **✗**

**DO NOT** use Chlorhexidine, Polihexanide or PHMB **✗**. These are toxic and will remain in the tissue for several days and prevent healing and Acapsil from working. Preferably antiseptics should not be used, but if absolutely necessary, use 70% Isopropyl alcohol **+**.

### **DO NOT let the wound become wet or moist.**

Avoid the wound, the Acapsil 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 Acapsil, wash and dry the wound and apply a new layer of Acapsil and secondary dressing – as described in sections 5, 6 and 7.

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

### **Store Acapsil refrigerated**

### **Keep Acapsil away from direct heat sources**

Avoid direct sunlight, radiators, window sills, pockets near to the body etc.

### **Use within 15 days of first opening an Acapsil bottle**

### **Minimise bottle contamination**

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

### **Occlusive dressings should be avoided**

### **Acapsil is intended for non-sterile wounds**

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

### **www.Acapsil.com**

Please visit [www.acapsil.com](http://www.acapsil.com).