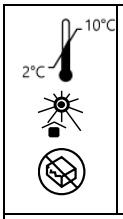
Acapsil®

INSTRUCTIONS FOR USE

Willingsford Healthcare

Powder for the treatment of wounds



DO NOT:

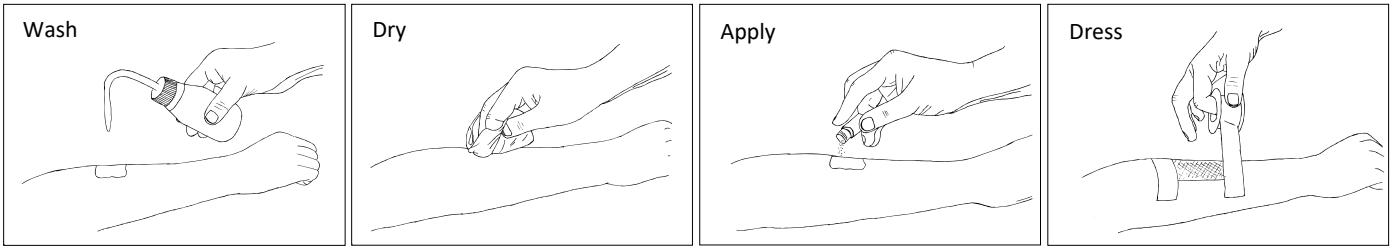
- Use if the bottle is damaged.
- Use if shelf life has expired (see bottle).
- Expose the bottle to a direct heat source.
- Combine Acapsil with any other topical products or therapies which may exert an effect directly on the wound.

DO:

- ✓ Store refrigerated (2°C to 10°C).
- ✓ Use within 15 days of first opening.
- ✓ Keep out of the reach and sight of children.
- ✓ Recycle both the bottle (HDPE) and cardboard box - according to local regulations. Non hazardous waste.

Manufacturer: Willingsford Ltd., NFEC, Rushington Business Park, Southampton, SO40 9LA, UK. contact@willingsford.com

ADVICE ON CORRECT PREPARATION, APPLICATION, USE AND AFTER-USE



WOUND PROCEDURE

Wound preparation

Debride the wound as much as possible using a, for the situation, appropriate method. Acapsil cannot work on eschar or very dry, old, thick necrotic tissue. This needs to be removed, e.g. by sharp debridement.

Clean the wound using saline or tap water.

Remove any undesired matter, e.g. slough and pus, as much as possible, e.g. using water and a swab. The use of, preferably, a wash-bottle or, alternatively, a large syringe will allow a good cleaning pressure without harming the wound bed.

If necessary, 3% hydrogen peroxide (H_2O_2) can be used initially as a light debrider. . Apply, allow for froth creation and wash off with water. When no froth is created, do not reapply. Do not leave on for longer than 30 seconds, and then wash off with water or saline. H_2O_2 is contraindicated in very deep or large wounds due to risk of gas embolism.

Do not use any products containing chlorhexidine, polihexanide, PHMB, iodine, octenidine or other antiseptics.

Dry the wound gently.

Dab it dry using a dry lint-free swab.

Apply Acapsil evenly in a layer of 1-3 mm.

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 of the skin. This would be the visible area with all crevices and beneath loose flaps and undermined areas, all sides of the wound and all surfaces lining tracts, tunnels, sinuses, fistulas, etc.

- Also, cover the wound edges well, extending to an area 2-5mm from the wound edge and onto the surface of the unbroken skin surrounding the wound opening.
- If the wound is on a vertical surface, e.g. on the lower leg of a sitting person, apply a 1-3 mm layer of Acapsil the size of the wound plus an extra 5 mm perimeter onto a dry, lint free swab or a permeable contact layer dressing. Use this as the secondary dressing by placing it directly over the wound and fix it there using sticking plaster tape.
- Sinus walls and cavities can be applied by depositing Acapsil on the flat handle of a wound probe, e.g. Advancis probe, or of an elongated spoon, carrying it down the tunnel and depositing it in the desired area. If the tunnel is large, it is possible to use a clean gloved little finger to ensure the distribution of Acapsil at the bottom and walls.

Cover with a light permeable secondary dressing.

To keep the Acapsil layer in place on the wound, cover it with a very light, dry and highly permeable to allow for evaporation of wound exudate and for establishing an aerobic environment that favours a well balanced microbiome.

We recommend 4 options:

A. 4-ply lint free swab 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 open woven gauze roll, tubular gauze or surgical stockinette (see Section “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.

Many contact layer 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 remove the exudate if used in combination with other topical products. The sole purpose of the contact layer dressing is to hold the Acapsil in place on the wound and wound edges. Acapsil is consequently applied *before* the contact layer.

If the contact layer dressing causes sensitivity, i.e. redness and/or dryness, do not use it, use option A or B.

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:

If the skin is so fragile that application of any adhesive to keep the gauze pad (Option B) or the contact layer dressing (Option D) in place is likely to break the skin upon removal, use only tubular gauze/stockinette. Alternatively, leave the Acapsil layer uncovered. Please see the section on Difficult-to-dress areas.

Remember:

Avoid applying pressure to the wound surface, e.g. by resting on the wounded area or by tightening shoe 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.

If the wound is heavily exuding, the *first* Acapsil application, and only the first, can be covered with a highly absorbent plain secondary dressing, e.g. Zetuvit Plus; Kerrafoam; Tegaderm without any active components, e.g. silver.

WOUNDS IN DIFFICULT-TO-DRESS AREAS - PROCEDURE

If necessary, a secondary dressing can be omitted. 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

Apply once daily.

Until the wound is clean, i.e. when the exudate is no longer cloudy and the wound is free of slough, pus, maceration and biofilm.

E. Suspension of dressing changes during week-ends during the period of reaching a clean wound has been used successfully. However, this may prolong the time required to reach a clean wound compared to daily changes.

If exudate reappears at a later stage in the healing process, use Acapsil as before until reaching a clean wound. One application is usually sufficient.

PROFUSELY EXUDING WOUNDS – PROCEDURE

Use the standard preparation, application and dressing procedures as described above. When the dressing is 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; an example could be after 4,8 and then after 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:

1. Remove all dressings as gently as possible. Proceed slowly and cautiously without jerking or tearing.
2. Gently clean the wound surface as described in section 4.
3. 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.
4. Very gently, remove as much loose necrosis and pus as possible without harming newly formed cells in the wound bed. E.g. wipe with a moistened lint-free swab.
5. Preferably, 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 unwished-for matter on the wound or wound edges. The water pressure allows effective cleaning of all corners and crevices whilst still taking care not to disturb any newly formed tissue in the wound bed, OR
6. If the wound cannot be thoroughly washed, wipe it very gently using a moistened lint free swab. In that case, 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 does not cause any harm.
7. Finally, repeat the application of Acapsil as described in the section "Wound procedure" under "Dry the wound gently"; "Apply Acapsil evenly in a layer of 1-3 mm"; "Cover with a light permeable secondary dressing" and "securing the dressing".

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 necrosis, slough and pus, please see below under complicated wounds.

DRESSING CHANGES ON COMPLICATED, NON-HEALING, CHRONIC WOUNDS AND/OR WOUNDS WITH AN EXTENDED INFILTRATION AREA

Debride as much as possible

Typically, any dry necrotic tissue will be softer than the previous day and can be lifted out or removed using sharp debridement. Loose, wet slough can be removed using a lint-free swab.

Complicated wounds will use the wound surface as the place to deposit the waste that is being cleared out from the deep and surrounding penumbral areas. This waste will typically, and unless the wound is very deep, be stuck to the secondary dressing and automatically be removed when the secondary dressing is gently removed. Usually, this waste will either be soft yellow slough or of a soft gel-like nature. Dependent on the circumstances in the surrounding tissue and penumbral area (e.g. deep tissue infiltration or partial necrosis or old blood residue (e.g. caused by prior packing dressings) it can, but does not necessarily, have a mucky appearance. Remove as much as absolutely possible of any unwanted matter.

If necessary, 3% hydrogen peroxide (H_2O_2) can be used as a light debrider.

Clean the wound thoroughly using sensibly pressurised water.

Using a wash-bottle to apply a good cleaning pressure will facilitate the cleaning of all corners, crevices, undermined areas, tunnels, etc of the wound without causing damage to the simultaneously granulating tissue in the wound.

Expectations to wounds in need of prolonged Acapsil therapy.

Acapsil is frequently able to provoke the re-initiation of the healing process in wounds that have not responded to any healing support for prolonged periods of time or in which the process is spinning out of control.

This lack of willingness to heal is frequently caused by complicating factors hidden outside our view, i.e. in the at times extensive penumbral area. While the penumbral area is being cleared and sorted, the wound will continue to deposit fresh slough and waste on the surface for days. Simultaneously, the wound will, typically, be granulating in some areas. The optimal way to help the wound get rid of the slough and waste without damaging the new granulation tissue, is by giving it a proper shower. Is this not possible, a similar experience can be achieved by the use of a wash-bottle supplying plenty of water with a reasonable pressure.

Expectations for wounds in need of prolonged Acapsil therapy – and signs indicating the wound is clean

As the wound progresses over days, the amount of waste material on the wound surface waiting to be removed at dressing changes will reduce. The gel-like structure of the waste material on the surface will change into a suspension-like structure (micro-granules in liquid) and the colour will change into a beige to off-white colour. This is a sign that the penumbral area is clean and that the entire area is on the course to healing. This can also manifest itself as the entirety of the, limited, exudate being of a healthy transparent nature (lymphatic fluid). Or the wound may quite simply show a healthy pink granulating surface with epithelialisation. These events are markers for discontinuation of the use of Acapsil.

DURATION OF USE - DISCONTINUATION

Once the wound has reached a clean state, application of Acapsil should cease as the wound will no longer benefit from its continued use.

This clean stage is usually reached within 1 to 5 days / applications.

A "clean" wound is free of slough, pus, maceration and biofilm.

Take care not to mistake lymphatic fluid (clear, transparent yellowish) for pus (cloudy yellow/orange/green/brown and foul-smelling). Lymphatic fluid is a healthy wound response and will diminish by itself without the use of Acapsil.

Dressed wounds - discontinuation:

The clean wound surface will typically have a moist and granulating healthy pink / red appearance and white – not grey or red - healthy looking wound edges.

This is highly desirable; the wound has exited the inflammatory healing phase and 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 epithelialisation 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 granulating or epithelialising, 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 secondary dressing was omitted, the clean wound will typically have a dry, pale red, flexible surface without a traditional scab, as well as white healthy wound edges.

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.

Complicated, non-healing, chronic wounds and/or wounds with an extended penumbral area and/or wounds in need of prolonged Acapsil therapy – discontinuation

Continue the use of Acapsil for as long as the wound continues to bring necrosis, pus and other waste material forward and depositing it on the surface where it will typically stick to the secondary dressing. Upon removal of the waste, the surface underneath will likely be granulating. Once the waste deposits turn into an off-white to beige colour and from a gel-like consistency into a suspension-like nature (tiny granules in liquid), the wound, including the penumbral area, has reached a clean state and Acapsil can be discontinued. In other types of wounds, the sign for discontinuation is simply that there is no more excess exudate or that the limited exudate is light-yellowish transparent (lymph). In the latter case, the granulation of the visible wound area will usually be quite advanced.

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 are now present in the wound favour healing and must be conserved. Similar to the conditions on the skin itself, this microenvironment is aerobic and needs access to the air. Dressings subsequently used must therefore be fully permeable (and non-occlusive) and allow air to reach the wound. Any adhesion to the proliferating 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 dressing every 2 or 3 weeks 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 therapy 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 occlusive devices 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) and the compression on top of this secondary dressing.

Acapsil has not been tested in conjunction with compression pumps.

ACAPSIL WITH PROTECTIVE DRESSINGS

Generally, occlusive dressings are not recommended. If a protective dressing is necessary, dress as described above under "Acapsil in conjunction with compression therapy" and apply the protective material following normal procedures. The protective bandage can be left in place for 1 to 3 days and in accordance with the recommended procedure for the chosen type of secondary dressing.

PRECAUTIONS

Acapsil is For External Use Only

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, it is recommended to minimize inhalation and exposure to the eyes.

Exposed nerve fascicles

If exposed nerve fascicles (large nerve bundles) are present in the wound, limit the application of Acapsil directly onto these to a very thin layer as excessive removal of moisture may cause irritation of the nerves.

DO NOT apply Acapsil to the eyes. In case of accidental application, immediately wash out eyes with plenty of saline; then seek medical attention.

OTHER INFORMATION

Acapsil is not absorbed by the body.

Acapsil can be removed by simple irrigation with water.

Systemic antibiotics can be administered in conjunction with Acapsil.

Standard clinical protocol should be followed for the treatment of any clinical infection.

Upon commencement and completion of a course of antibiotics, expect a 24-48 hours delay or setback in the wound healing process.

This is relevant for wounds actively receiving Acapsil and wounds continuing the healing process after discontinuation of Acapsil.

DO NOT combine Acapsil with any other topical treatments or therapies.

These may impact the pumping capacity of Acapsil (examples of topical treatments to avoid: Negative Pressure Wound Therapy, honeys, silver, iodine, topical antibiotics (both as ointment, creams, gels and powder), collagen, gels, gelling agents, octenidine, polihexanide, PHMB, occlusive absorbent dressings (e.g. alginates) 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, PHMB, octenidine, iodine or silver prior to Acapsil application.

These antiseptics are cytotoxic and will remain in the tissue for several days. If necessary, as an alternative antiseptic and light debrider, use 3% hydrogen peroxide (H_2O_2) solution.

AVOID the wound becoming wet or moist.

Avoid the wound, the Acapsil layer and the bandage getting wet or moist from any external sources, e.g. washing, or internal sources, e.g. sweating.

If it happens, clean off the old Acapsil, wash and dry the wound and apply a new layer of Acapsil and secondary dressing – as described above.

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.

Direct sunlight, radiators, window sills, pockets near to the body, hot cars etc.

Use within 15 days of first opening of Acapsil bottle.

Prevent cross-contamination

Wash or disinfect hands or change gloves after preparing the wound and before touching the Acapsil container.

If necessary, use alcohol or isopropyl alcohol to wipe off Acapsil bottle.

If necessary, reserve Acapsil container for single patient use.

Occlusive dressings should be avoided.

Acapsil is intended for non-sterile wounds.

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

Container sizes

750 mg; 2 g; 3 g; 6 g; and 10g.

www.Acapsil.com

Instructions for use by layperson are available on www.Acapsil.com under How to Use. This can e.g. be useful if the patient is to use Acapsil at home.