USertaSil[®]

INSTRUCTIONS FOR USE



- ^{10℃}	DO NOT:	DO:
2°C	 Expose the bottle to a direct heat source. 	\checkmark Keep SertaSil [®] out of the reach and sight of children.
×	 Use if the bottle is damaged. 	✓ Store refrigerated (2°C to 10°C).
瀿	 Use if the shelf life has expired (see bottle). 	✓ Use within 15 days of first opening.
8	Combine SertaSil [®] with any other products or therapies which may exert an effect directly on the wound.	 Recycle both the bottle (HDPE) and cardboard box according to local regulations.
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INDICATION:

Treatment and prevention of infection and support of healing of all types of acute and chronic wounds, trauma, ulcers and burns, including surgical wounds, necrotising fasciitis (flesh-eating infection), open abscesses, cuts, lacerations, puncture and degloving wounds, and skin infections.

INDICATED FOR:

Canines, Equines, Felines, Rabbits, Elephants, Primates, Birds, and other terrestrial Animals. Limited experience with Reptiles and Amphibians.

GUIDANCE FOR PREPARATION, APPLICATION, USE AND AFTER-USE: Wash Dry Apply Dress

PROCEDURE

Please read these instructions in full before using SertaSil[®].

1. Inspect and prepare the wound

Remove any foreign body, e.g. a thorn or piece(s) of grit. If you suspect a bone or tendon could be broken, or the joint to have been punctured, consult a veterinarian.

Debride the wound, i.e. remove dirt, pus, dead tissue, slough, any very old scabs or other evidently inappropriate material.

2. Clean the wound thoroughly

Use clean tap water for washing the wound. Alternatively, use clean, bottled drinking water, not saline.

- Small animals: use a hand-held shower head in the shower, -- Large animals: use a hose.

Wash thoroughly with a relatively high water pressure from all angles for as long as it takes for the water to remove all pus, dead tissue, slough, dried debris and anything else that does not belong in a healthy, healing wound.

If the use of the above is completely out of the question, use a large wash-bottle (similar to the one shown in the first picture above) to provide plenty of water at a good cleaning pressure.

DO NOT USE # antiseptics or ANY type of cleaning solutions containing any antimicrobial ingredients. Examples are Chlorhexidine (e.g. Hibiscrub), Iodine (e.g. Betadine and including cadexomer and povidone), Silver or Nano-silver, Polihexanide, PHMB, Polyaminopropul biguanide (e.g. Prontosan), Octenidine, Cetrimide, or Gentian violet/Crystal violet in any form **×**.

If the wound is a bite wound, a puncture wound, or you suspect that very harmful contamination of the wound has occurred, use a 3% hydrogen peroxide (H₂O₂) solution before washing on the first few days. Do not use a stronger solution of H_2O_2 .

If the wound is full of pus and dead tissue that you cannot possibly remove by washing as above, use a moist gauze to gently help this out of the wound. If this still does not allow you to remove the debris, a 3% hydrogen peroxide (H₂O₂) solution can also be used.

- H₂O₂ Method: Use only when necessary. Apply the hydrogen peroxide (H₂O₂) solution, allow for froth creation, when this wears off, wash it off and repeat. Do not leave each application on for longer than 20-30 seconds. Cease repeating application once no froth is created upon application; do not repeat more than 7 times. Then wash the wound with tap water as described. H₂O₂ should not be used in very deep wounds as there is a risk of gas embolism. Use only for a few days.

SertaSil[®] cannot work on a completely dry surface. Please see how to proceed below in the section "Eschar and completely dry surfaces".

3. Dry the wound gently

Dry the wound by gently dabbing it till it is moist - not dried out. Leave no standing water. Use a dry swab, gauze pad or clean towel.

4. Apply the SertaSil®

On all wounds:

i) Sprinkle SertaSil[®] in a 1mm unbroken layer directly onto the entire wound surface, including beneath loose flaps of skin and any undermined areas. Ensure all crevices are covered and leave no openings in the covering. Apply as much SertaSil[®] as will stick to the wound surface. Use your finger or a swab to ensure all areas are well covered. The underside of any affected flaps of skin can be covered by applying SertaSil[®] to a dry gauze and dabbing upwards.

ii) Cover the wound edges well.

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iii) Rub or massage SertaSil[®] into any reddened, swollen, cracked and/or unusually warm skin surrounding the wound opening. Extend this application 5 mm onto the completely normal, healthy-looking skin. Make sure the powder reaches the skin and is not simply caught in the fur. If required, shave off the fur in the relevant area. If required, pass a moist swab over the skin immediately before application to help the powder stick to the skin.

If the wound is on a vertical surface, prepare the gauze pad with tape on all four edges. Fasten to the skin the side of the dressing closest to the ground. While sprinkling SertaSil[®] in sections from the bottom upwards to the surfaces mentioned above, gradually fasten the taped gauze to the skin along the sides. This is to help with the application and to ensure the SertaSil[®] is kept in place. Alternatively, apply the SertaSil[®] directly onto the gauze while applying the gauze as described.

In addition - On deep wounds, cavities, and tunnelling:

Sprinkle SertaSil[®] into the cavity and use a gauze swab or your gloved finger to even it out and cover the entire surface, of the sides and bottom. A cavity should not be filled up with powder. The thickness of the layer should, like in all wound types, be determined by the amount that sticks to the surfaces.

Ensure SertaSil[®] covers all surfaces lining any tunnelling and reaches as far towards the bottom of any tunnel as possible. Even application can often be achieved by applying SertaSil[®] as far into the tunnel as possible followed by moving or very gently "shaking" the tissue around the wound. A 3 ml single-use pipette can help precision in the application process.

In addition – On wounds with a wide inflammation area:

Inflammation extending far from the wound edges or patches of inflammation in the vicinity of the open wound indicates that the infection has infiltrated the underlying tissue and is spreading further. Massage a thin, but unbroken film of SertaSil[®] into the affected, reddened skin. Extend this coverage at least 5mm onto non-inflamed, non-affected skin along the whole periphery. This is to block further spread.

5. Apply a covering dressing (optional)

A covering cotton gauze is not required. Omitting the dressing should always be preferred if the dressing could potentially interfere with unhindered air access. For details, please pass directly to the section "Wounds in difficult-to-dress areas" below.

To keep the SertaSil[®] layer in place on the wound, it can be covered with a single 2 or 4-ply thin, woven, gauze pad made of 100% pure cotton. Access to air promotes an environment favourable to healing and permits evaporation as required for SertaSil[®] to work optimally.

Any dressing or additional supporting devices made of synthetic materials must not be worn.

6. Securing a dressing (optional)

Fasten the woven 100% pure cotton gauze using sticking plaster tape. The tape should not pass over the wound area or any inflamed skin 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 gauze pad).

Suitable tapes differ according to the strain sustained during movement. Examples of tapes that seek to reduce allergy (sensitivity), pain and pulling out fur when removed are Leukosilk[®] and Urgofix[®].

On abdomen and legs, the cotton pad can be substituted by a 100% cotton open woven gauze roll. The gauze should pass

over the wounded area no more than 1 or 2 times. Tying the ends in a knot can prevent any use of tape. Make sure the knot is not on top of the wound.

7. Minimise the time SertaSil[®] is outside the refrigerator.

WOUNDS IN DIFFICULT-TO-DRESS AREAS

SertaSil[®] can be used without an extra dressing or bandage. Following application (see above) leave a little time for it to settle onto the entire damaged area, before allowing the animal free movement, as any loose powder will fall off. Without covering, SertaSil[®] is at risk of wearing away sooner and may therefore need to be reapplied more frequently, e.g. twice daily instead of once, in the early treatment of severe wounds.

ENSURE GOOD ACCESS TO AIR AT ALL TIMES

Access to air is required for SertaSil[®] to work properly. Air also favours a composition of the wound microbiome that supports healing. Therefore, avoid blocking the access of air. E.g.: Do not allow the animal to rest on the wounded area or to place the wound up against an object such as a pillow or side of bed.

FREQUENCY OF APPLICATION AND DURATION OF USE

Apply SertaSil $^{\ensuremath{\mathbb{S}}}$ once every day until all dead tissue and infection is gone.

The infection is gone when the following features have disappeared: smell, discharge, old dead tissue, brownish or purple/strong-red soft tissue, tunnels, red or damaged skin, nodulous skin, swelling.

If any of the above features reappear at a later stage in the healing process, use SertaSil[®] as before until the wound is clear.

Once the entire wound is free from infection and has reached a healing state, application of SertaSil[®] should cease. SertaSil[®] enables the body's immune system to proceed with the natural healing processes, rendering continued use of SertaSil[®] unnecessary. If the animal is immunocompromised, the immune system will require the support of SertaSil[®] for longer.

Signs of healing include: no wound exudate: no odour; moist, shiny, pink coloured wound bed; uneven "budding" wound bed; white or light grey moist (not wet) wound edges, fine brown film (moist or dry) covering the wound edges; a scab that does not leak any sort of liquid upon daily prodding.

In acute wounds only treated with SertaSil from the start, this infection-free, healing stage is usually reached within 1 to 5 days of first application. If antimicrobials have been used, or if the wound is old and chronic, it may take longer.

The features of healing may appear in different areas of the wound on different days. SertaSil[®] should only be discontinued when the entire wound is infection free.

Do not to mistake lymphatic fluid (transparent, yellow-tinged 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 SertaSil[®].

What to expect

The wound will normally start re-generating new soft tissue from the bottom of the wound bed making the wound shallower. Simultaneously and subsequently new skin will move in from the wound edges and can on rare occasions appear as whitish isles in the wound bed.

PROFUSELY EXUDING ('WEEPING') WOUNDS

If the wound is oozing (exuding, discharging) uncontrollably, the most effective way to use SertaSil[®] is to follow the standard

preparation, application and dressing procedures described above. When the dressing is completely *soaked*, or the powder come out mixed into the discharge, change the SertaSil[®] 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. The level of discharge usually reduces quickly - within 24-48 hours - provided air is allowed access to the wound.

When the SertaSil[®] no longer has a soaked appearance within 8 to 12 hours, continue as described in the section "Frequency of Application".

ESCHAR AND COMPLETELY DRY SURFACES

SertaSil[®] cannot work on a completely dry surface as seen in hard, dry, usually black, eschar, or in very thick, brown, leathery-dry eschar. Such eschars need to be removed using sharp debridement. Once debrided, proceed in the usual way described above.

If sharp debridement cannot be performed, make openings in the dry hard surface and apply SertaSil[®] into these as well as under the edges of the eschar. SertaSil[®] will work from these openings and the autolytic debridement will gradually soften the eschar enabling its progressive removal.

If necessary, 3% hydrogen peroxide (H_2O_2) can be used as a light debrider – see instructions above under section 2 "Clean the wound".

TREATMENT CHANGES

Once daily, follow these steps:

- i) Remove the dressing slowly and cautiously without jerking or tearing. Removing any tape in the direction *with* the hair usually avoids excessive loss of hair.
- ii) If SertaSil[®] has been applied correctly, i.e. covering the entire wound surface and edges, the covering gauze will not stick to the newly formed cells in the wound bed. Should it seem lightly stuck, the substance adhering to the dressing is usually of a gel-like consistency and contains debris from the infection, which needs to be removed from the wound.
- iii) Wash the wound thoroughly with plenty of clean tap-water (alternatively bottled drinking water) from all angles to remove all loosened debris. Do not wipe the wound or remove anything by hand. Apply a reasonably high water pressure to allow effective cleaning of all corners and crevices. Once the wound edges are covered with a thin grey/brown film - soft or dry-ish - do not remove this protective coverage, unless it falls off during washing.
- iv) If scab is present, see the section "Scab formation" below.
- v) Repeat the application of SertaSil as described above under section 4.

Scab formation

A scab can move in from the sides like a "film" acting as a front for novel skin cells. Do not touch or rub this.

A scab can provide a dry, pale red, flexible surface with white healthy edges. Do not touch or rub this.

Or, a scab can cover the entire wound surface at once with a hard non-flexible surface. Infection can appear underneath this "lid". Therefore, a hard scab MUST be checked daily: Every day, gently but firmly press down on the scab at a 90-degree angle and watch for a drop of liquid appearing from anywhere under the scab. If this happens, the scab must be removed and followed by the usual, thorough washing and application routine. If no liquid appears when prodding, the scab should remain in place. If the use of SertaSil is continued to prevent reinfection, perform the usual washing and application routine. Make sure the SertaSil[®] reaches into all the crevices of the scab and push it gently under the edges of the scab without disturbing or lifting the scab. The wound will release the scab when ready.

If a healthy scab is removed prematurely, or if infection is allowed to proceed underneath an unhealthy scab, healing will suffer a set-back and will cause unnecessary scar formation.

Do not mistake a scab for eschar. Eschar appears early, or in the non-healing wound and indicates infection. Scab appears later, and only in a healing part of a wound.

"Flakes" and "scales"

Thin flakes often appear on the apparently healthy skin next to the wound and on newly generated skin covering the wound. Flakes should not be removed. They should be ignored and will fall off in their own time. Flakes are NOT a sign of dryness. NO creams, moisturisers, oils or similar should be applied to the skin for as long as the flakes are still present, including long after full closure. Leaving the flakes alone, ensures the best quality of the generated, still remodelling tissue.

SERTASIL[®] WITH PROTECTIVE DRESSINGS

Generally, dressings which prevent air circulation to the wound must not be used. Occlusion promotes an unhealthy microbial environment and prevents evaporation which is a requirement for SertaSil[®] to work properly.

AFTER DISCONTINUATION OF SERTASIL® TREATMENT

When the treatment with SertaSil[®] ceases, the wound should now be left in peace to close fully 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 whilst using SertaSil[®], this microenvironment needs unhindered access to air.

Wash the wound once daily as usual with clean tap water or drinking water and nothing else. Preferably, leave the wound undressed and fully exposed to air. Like before, avoid all types of impregnated dressings and all self-adhesive dressings.

If a dressing must be worn, dusting the wound surface with a very thin but unbroken layer of SertaSil will prevent the pure gauze dressing from adhering to the healing wound bed. If adhesion occurs, gently loosen the gauze under running tepid tap water.

If the wound gets wet, soiled, or sweaty, wash it thoroughly using only clean tap water or drinking water, dab it dry and if the soiling was severe, apply a dusting of SertaSil[®].

AFTER CLOSURE

After full wound closure, allow 6-8 weeks for the area to mature and regain strength. The wounded area will continue to regenerate, reconstruct, and strengthen the tissue underneath the skin, the skin itself, and the fur for months and even years.

PRECAUTIONS

Do not eat SertaSil[®].

All ingredients are non-toxic.

No adverse events have been recorded after dogs ingesting $\mathsf{SertaSil}^{\circledast}$.

Keep SertaSil[®] out of the eyes.

Should that occur, immediately wash out the eye(s) with plenty of water or saline (mild 0.9% salt solution) and seek veterinary assistance.

OTHER INFORMATION

SertaSil[®] is For External Use Only

SertaSil® is not absorbed by the body.

SertaSil® can be removed by simple irrigation with water.

Toxicity

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

No adverse events have been recorded after daily use of SertaSil[®] directly on bone, tendon, ligaments and vessels for very prolonged periods of time (as used in palliative care).

AMR

SertaSil[®] is effective on antimicrobial resistant infections.

SertaSil[®] does not create or contribute to AMR.

Antibiotics

Antibiotics will slow down healing.

Systemic antibiotics can be administered in conjunction with SertaSil[®] for issues unrelated to the wound. Upon commencement and completion of a course of antibiotics, expect a 24-48 hours delay or setback in the wound healing process.

In very complicated/severe wounds in immunocompromised animals, antibiotics may stall healing completely until completion of the antibiotic course.

Topical antibiotics cannot be used in conjunction with SertaSil® ×.

DO NOT combine SertaSil[®] with any other treatments or therapies applied directly to the wound.

These will impact the actions of SertaSil[®]. Examples of topical (i.e. applied on top of the wound) agents and treatments to avoid 🖊 are:

- Honey
- Silver Gelling agents
- Iodine Octenidine
- Nanosilver
 Polihexanide Cetrimide
 - Chlorhexidine • Alginate

Gels

Collagen

- Polyaminopropyl Biguanide Gentian violet PHMB
- Topical Negative Pressure Wound Therapy (vacuum pump)
- Topical antibiotics as ointment, cream, gel, and powder.
- Absorbent dressings which are impermeable to air ('occlusive') e.g. foams, alginates, 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 **×**.

Hydrogen peroxide 3% solution

(H₂O₂) can be used as described in Section 2 "Clean the wound". Hydrogen peroxide can support the immune response. Do not use hydrogen peroxide in wounds with underlying osteomyelitis (bone infection), or exposed organs.

DO NOT use occlusive (air-tight) dressings.

A covering dressing is not required.

The sole purpose of any covering pure cotton dressing is to hold the SertaSil[®] in place on the wound and wound edges.

DO NOT let the wound become wet or moist.

Avoid the wound, the SertaSil® layer and the dressing getting wet or moist from the outside, e.g. from licking, rain or puddles, or from the inside, e.g. from sweating.

Should that occur, clean off the old SertaSil[®], wash and dry the wound and apply a new layer of SertaSil[®] and secondary dressing - as described in the section "Treatment changes". In case of excessive sweating, consider the option not to cover SertaSil[®] with a secondary dressing (cotton gauze).

Use within 15 days of first opening a SertaSil[®] bottle.

Store SertaSil[®] refrigerated.

ALWAYS return the SertaSil[®] bottle to the fridge *immediately* after use.

Keep SertaSil[®] away from direct heat sources

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

ALWAYS transport SertaSil[®] refrigerated.

Minimise bottle contamination

If a SertaSil $^{\ensuremath{\text{B}}}$ bottle has touched the wound, use alcohol or isopropyl alcohol to wipe it clean.

Doping

The ingredients of SertaSil® are not regulated by the International Doping Agency or FEI.

Withholding times

SertaSil[®] is not associated with any withholding times.

Environmental impact

SertaSil[®] only contains natural ingredients that are readily reintegrated into the biological cycles.

The use of SertaSil[®] does not involve any, synthetic polymers, e.g. plastics, chemicals, or antimicrobials.

This favours biodiversity and reduces the impact of wound care on climate change.

SertaSil[®] is a One Health product.

Container sizes

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

Please visit www.willingsford.com

Videos of how to use the treatment are available on the website. Scientific and medical publications on MPPT are also available. MPPT is the generic name of SertaSil[®].