Please read this information leaflet carefully. Please follow the instructions when using this product.

Hyiodine®

Product information
HYIODINE® is a primary, sterile non-adhesive, and atraumatic wound dressing suitable for covering, cleaning and hydrating deep wounds and skin defects. It ensures suitable healing conditions and its lubricating properties are ideal for preventing gauze adhesion to wounds.

Application
During application, the principles of appropriate hygiene and cleanliness should be maintained. HYIODINE® can be applied in several ways, depending on the size and characteristics of the wound.

Minor defects (small cuts or lacerations, minor superficial wounds, e.g. leg ulcers up to 3 cm^2 surface area)
In small defects, HYIODINE® is applied directly on the wound (best with the help of a sterile syringe), and after that, the wound should be covered with a sterile dressing (lint free, textile dressing, or plaster). The dressing should be changed at one to three day intervals until the wound is completely healed.

Major defects (all types of wounds, superficial, deep, infected as well as noninfected, diabetic foot ulcers, pressure ulcers, leg ulcers, dehisced surgical wounds or wounds that have been left to heal through secondary intention)
For the treatment of major defects (more than 3 cm^2 surface area), HYIODINE® is applied with the help of sterile unwoven fabric or sterile gauze. The appropriate amount of HYIODINE® is applied onto the non-woven fabric or gauze with a sterile syringe. The HYIODINE® is worked into the fabric/gauze by fingers until it has become saturated. If you press the saturated gauze between two fingers, you should be able to squeeze out a small amount of HYIODINE®. The recommended volume of HYIODINE® depends on the size of the non-woven fabric or sterile gauze: 2 ml on 5 x 5 cm square, 5 ml on 7,5 x 7,5 cm and 7–8 ml on 10 x 10 cm. Depending on the type of fabric used darkening of the material may be observed during application of HYIODINE®. This does not impair efficacy of HYIODINE® and should not cause any concern. The user should ensure that the fabric or gauze is completely saturated with HYIODINE® as incomplete saturation of the dressing may cause it to stick the wound with a subsequent decrease in efficacy of the preparation and potential trauma to the wound. Once the fully saturated dressing has been applied to the wound, it should be covered by a suitable secondary absorptive dressing. The choice of secondary dressing should reflect the exudate output of the wound. The dressing is subsequently retained in place with a bandage or adhesive tape.

Cavities and fistulae
Smaller cavities or fistulae can be directly filled with HYIODINE® injected by syringe. The wound is then covered by a gauze immersed with HYIODINE® and this is finally covered by an appropriate secondary dressing. For the management of deep cavities or fistulae a small amount of HYIODINE® should be injected directly into the fistula canal. The defect is further filled with a gauze well saturated with HYIODINE® which is used as the fistula drain. Cavities should be well filled by sterile gauze saturated with HYIODINE®. Small piece of the fistula drain or gauze filling should always protrude from the fistula or cavity, to facilitate drain removal when redressing the wound. Once the wound is dressed with HYIODINE® it should be covered with suitable secondary dressing. The dressing is subsequently fixed in place with a bandage or adhesive tape.

Further possibilities of the application of HYIODINE®
For the management of superficial non-infected wounds HYIODINE® may be applied by use of a polyurethan foam dressing. A suitably sized sterile polyurethan foam should be cut to the approximate shape of the wound. HYIODINE® is applied uniformly on the wound side of the foam by means of a sterile syringe and the HYIODINE® impregnated foam is placed on the wound. The wound is further covered by a suitable secondary absorptive dressing and subsequently fixed with a bandage or adhesive tape.

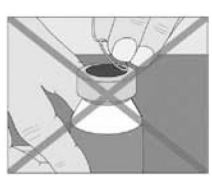
In combination with paraffin impregnated gauze (suitable for the treatment of superficial dry wounds) HYIODINE® is applied directly to the wound and subsequently covered with the paraffin gauze dressing. A secondary absorptive dressing is then put on the wound and retained in place with a bandage or adhesive tape.

The frequency of redressing
After the first application of the preparation, it is recommended to change the dressing within 24 hours. In infected wounds, it is essential to change dressings daily. Once wound inflammation has subsided, dressing change may be extended to every two or three days. In noninfected wounds, further redressing is possible 48 or 72 hours later. In wounds with moderate to high levels of exudate, it may be possible to change only the outer covering dressing that has absorbed the exudate in this case, leaving the inner dressing that is saturated with HYIODINE® in place. It is recommended that the wound is dressed in the aforementioned manner until healing is complete. If the wound deteriorates then re-assessment is indicated.

The textile fabric or gauze should be **completely** saturated with the HYIODINE® before application to the wound to ensure that it does not stick to the wound. During dressing procedures, it is necessary to ensure wound edge protection to avoid adherence of the dressing to newly formed epithelium (skin). If the dressing adheres to the wound bed or the wound edge, it indicates that an insufficient volume of HYIODINE® has been used in the preparation or alternatively that the dressing has been left on the wound for too long. In the case of the dressing adhering to the wound, it is necessary to moisturize the dressing before removal, e.g. with saline solution and to treat the edges of the wound with a different ointment before the next dressing application.

The recommended use of vials closed by a rubber plug and an aluminium top

Remove the vial from the box and peel off the white part of the top. Clean the uncovered plug with a disinfecting agent containing alcohol or with the disinfecting agent appropriate for skin.



When used at home, it is not recommended to take off the aluminium part of the top. Do not peel of the aluminium ring!

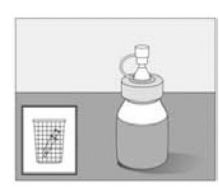
Use the enclosed spike only for purposes described here. Take the spike out of the package and remove the protective cap. Be very careful while handling the spike to avoid the risk of injury.

After removing the protective cap, stab the spike into the HYIODINE® vial **immediately** through the uncovered part of the plug.

Remove the cap of the upper part of the spike.

Insert the sterile syringe into the aperture in the upper part of the spike.

Turn the vial up together with the inserted syringe and withdraw the needed amount of HYIODINE® into the syringe.



Keep the spike inserted into the vial and close it with the protective cap. Discard the used syringe appropriately.

It is also possible to withdraw HYIODINE® from the uncovered part of the rubber plug by means of a sterile syringe and a needle. If the syringe and needle are not available, remove the aluminium top by pulling the aluminium ring, remove the rubber plug and apply the preparation on the wound or dressing. After use, close the vial tight with the rubber plug. Store the vial in cool environment (2–8 °C), after opening and use within 6 weeks of opening.

Description
HYIODINE® is a sterile viscous solution of sodium hyaluronate. The colour of HYIODINE® is red-brown.

Composition

Sodium hyaluronate	1.5 g
KI	0.15 g
I_2	0.1 g
Injection water	ad 100 g

Characteristics
Sodium hyaluronate /poly(8-sodium-D-glucuronate-[1-3]-N-acetyl-D-glucosamine-[1-4])/ is a linear, negatively charged polysaccharide. It is a naturally occurring component of the organism (especially the extracellular matrix) and as such, it is non-toxic and does not cause allergic or other hypersensitivity reactions. Sodium hyaluronate has unique physical and chemical properties, high hydration capacity and excellent anti-adhesive properties, creating conditions conducive to natural wound healing.
Iodine and potassium iodide are used to prevent the rapid decay of sodium hyaluronate by bacteria present in and around the wound.

Indications
HYIODINE® is used to cover, clean and hydrate deep wounds and skin defects, in particular deep pressure ulcers (bedsores), diabetic defects, crural ulcers, burns, post-operation wounds, difficult-to-heal wounds and large abrasions. HYIODINE® is also suitable for the treatment of infected wounds. Its hydrating properties prevent the dressing from sticking to the wound and it maintains conditions suitable for the wound to heal. The use of HYIODINE® in extensive and infected wounds should be always consulted with a physician.

Caution
Individuals suffering from thyroid problems should consult their physician prior to the use of HYIODINE®. On application of HYIODINE®, iodine present in the product may transform into iodide, which is necessary for the production of the thyroid hormone. In patients using other iodine preparations, it is necessary to consult the used dose with a physician.

Contraindications
No adverse effects are known for local application of sodium hyaluronate.
Iodine contained in this product may cause allergic reactions in persons sensitive to iodine.

Adverse effects
Sodium hyaluronate is well tolerated. At present, there are no known adverse effects after local application. Iodine contained in this product may cause allergic reactions in persons sensitive to iodine. No such reactions have been observed in the use of HYIODINE®.

Pain
During the first 20 minutes after the application of HYIODINE®, the patient may feel pain or transient burning in the place of the wound. Itching or burning may occur especially in patients suffering from leg ulcers. These reactions are caused by oncotic pressure in the wound after dressing or by temporary irritation of nerve endings in the wound due to the iodine. The pain should gradually reduce during repeat application. Pain caused by unsuitable dressing (most commonly excessively tight dressing) should be avoided. If these problems persist, contact your physician.

Erythema
Reddening of the skin around the wound may indicate inadequate replacement of the upper layers of gauze and subsequent maceration of the skin. Reddening around the wound may also occur in cases of complicated deep wounds with an infection and inflammation under the surface of the wound. This process is usually accompanied by severe pain and swelling, and is not caused by the application of HYIODINE®. If these problems occur, it is advisable to seek an examination by your physician and consultation on how to proceed in the treatment.

An increased blood supply to the wound, indicated by reddening or slight bleeding during the redressing of the wound (particularly with ulcers) does not complicate the healing process. It is a sign that new granulation tissue is forming; this tissue closes the defect and is an essential part of the healing process.

Please inform your physician regarding any adverse effects or other unusual reactions immediately.
Please report any serious adverse effects of HYIODINE® to the manufacturer:
Contipro Pharma a.s., Dolní Dobrouč 401, 561 02 Dolní Dobrouč, CZECH REPUBLIC
phone: +420 465 520 035, fax: +420 465 524 098, e-mail: sales@contipro.com

Interaction
Solutions of sodium hyaluronate become turbid (opalescent) or coagulate after mixing with compounds which have positive charges (e.g. some cation antibiotics: Gallimycin, Cobactan; polysaccharides: e.g. Chitosan; preservatives: e.g. benzalkonium chloride; detergents, etc.).
Therefore, HYIODINE® should not be mixed or applied together with other medical products or drugs.

Warnings
For external use only.
If contact with eyes occurs, it is recommended to rinse the conjunctival sac with lukewarm water.
Do not use the product if the packaging has been damaged.
Do not use the product after accidental spillage and direct contact with non-sterile surfaces.
Do not use after the expiration date specified on the packaging.
Do not use if the gel of the product changes colour. This indicates that the iodine concentration has reduced and therefore there is an increased possibility that the product is contaminated and has reduced efficacy.
Once open, store the product in a cool place (2–8 °C), use within 6 weeks of opening.
Keep out of the reach of children.

Packaging
HYIODINE® is supplied in glass bottles. Each bottle contains min. 50 g /22 g of HYIODINE®.

The content of the package
HYIODINE® vial, Extra-spike SK, enclosed information.

Shelf life
24 months. Use within 6 weeks of opening.

Storage
Store at a temperature of up to 25 °C. Once the product has been opened, store it in a cool place (2–8 °C); out of direct sunlight. Protect from freezing.
Prior to application, HYIODINE® must be brought to room temperature.

Manufacturer
Contipro Pharma a.s.
Dolní Dobrouč 401
561 02 Dolní Dobrouč
CZECH REPUBLIC

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05/2012

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Symbols used

CE 1023	CE MARK
LOT	BATCH No.
	REFER TO INSTRUCTION LEAFLET!
25 °C / 2 °C	TEMPERATURE LIMITATION
STERILE A	STERILE USING ASEPTIC PROCESSING TECHNIQUES
	EXPIRATION DATE