



SOLAR LENTIGO

Treatment guidance

HYDR  ZID[®]

Solar lentigo

Solar lentigo, also called “lentigo senilis”, “liver spots” and “age spots”, is a benign skin change that involves hyperplasia of the epidermis and increased pigmentation of the basal layer¹.

The changes in the skin are caused by exposure to sun and therefore occur in sun-exposed areas of the body such as the face, the back of the hands, shoulders and back^{1,2}. The changes may develop slowly over several years or occur suddenly^{1,2}.

Lentigines vary in appearance from light brown to dark or black spots on the skin, from oval to irregular, and in some cases with nodules in the lesions or slightly scaly. They also vary in size from a few millimetres to several centimetres in diameter. The changes often get darker and grow larger proportionally with age^{2,3}. Lentigo occurs on sun-exposed skin and most frequently in fair-skinned people.

The prevalence of solar lentigo is higher in fair-skinned people who have been exposed to too much sun².

Children with the hereditary skin disorder xeroderma pigmentosum develop solar lentigo during their first months of life, even with a minimal degree of exposure to sun⁴.

Solar lentigo may be cosmetically unsightly for some patients, causing them to seek treatment.



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What is Hydrozid®

- Hydrozid® is an innovative CE-marked medical device that combines traditional cryosurgery with modern aerosol technology. Its patented, unique application system provides a safe and effective method for treatment of solar lentigo.
- Hydrozid® contains the gas norflurane and exposes the lesion to temperatures as low as -54°C to -58°C by means of a concentrated jet.^{5,6} The consistent treatment temperature of less than -50°C lasts for up to 4.5 minutes after treatment start and thus ensures a unique cold potential within cryosurgery. The necessary temperature for destroying benign cells using cryosurgery is between -20°C and -30°C , while for premalignant cells it is between -40°C and -50°C .^{7,8}
- The varying reaction of skin cells to the low temperatures of cryosurgery enables the treatment of epidermal cells without damaging subcutaneous connective tissue, fibres or immune cells.⁷ Having increased their melanin production due to the sun's UV radiation, the melanocytes are highly sensitive to cryosurgery and are easy to destroy with small doses and short exposure times¹.
- Hydrozid® treatment is based on the methods of freeze-thaw cycles and temperature control. Rather than continuous treatment exposure, studies have shown that repeated exposures to freezing followed by thawing (a freeze-thaw cycle) enhance the effect by up to 100%.⁹ These cycles afford the therapist more control of the treatment temperature and its effect on the treated area, which helps prevent overtreatment.¹⁰

Hydrozid® treatment is approved for children and adolescents.

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Inform the patient before treatment

Provide the patient with the Hydrozid® patient instructions.

The patient instructions give relevant advice and information in brief about the treatment process.

The patient instructions are available free of charge at <https://shop.hydrozid.eu> or by email: info@hydrozid.com.

Application template

When treating solar lentigo, use one of the accompanying application templates to protect the surrounding healthy tissue during treatment.

The application templates have holes in 6 different sizes (3-10 mm in diameter). If the solar lentigo is larger than 10 mm in diameter, treat it as described in the treatment section *Treatment of lentigines larger than 10 mm*.

When treating solar lentigo, it is advisable to apply treatment to 1 mm of the healthy skin surrounding the margin of the change in order not to leave out any pigmented cells¹¹. You should therefore use the hole in the application template that covers the change and 1 mm surrounding the change.

The treatment margins may become blurred during treatment as the formation of ice

crystals covers the delimitation of the change and the surrounding healthy tissue. The application template can thus help focus on the limits of the change during treatment.

You can also use the application templates' size indications to compare the size of the change after each procedure to assess the effect of treatment.

The application templates can be used to treat more lentigines on the same patient, after which they must be discarded.



Application template

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Treatment of one solar lentigo

Treatment steps using Hydrozid®

After unpacking – do not remove the tip of the application tube. It must remain in place during treatment.

1. Release the locking mechanism under the activation arm, from left to right. The canister is now ready to use.



2. Hold the application template in place above the change with your non-dominant hand.

Hold the Hydrozid® canister in your dominant hand as vertically as possible. Push lightly on the trigger until you hear a hissing noise and the gas is released. If you push the trigger too hard, the sound will be more like when dispensing a deodorant spray, which releases unnecessary amounts of gas with a risk of damaging surrounding healthy tissue. Also, this is not an economical use of the gas.



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3. Spray at a distance of 2-3 centimetres from the solar lentigo, for up to 3 seconds. A film of white ice crystals will now form in the treated area. Start counting when ice crystals start forming on the change¹². After (up to) 30 seconds, the ice crystals are no longer white, indicating that the thawing period has ended. The first freeze-thaw cycle is now completed.



A distance of 2-3 centimetres corresponds to about 2 finger widths.

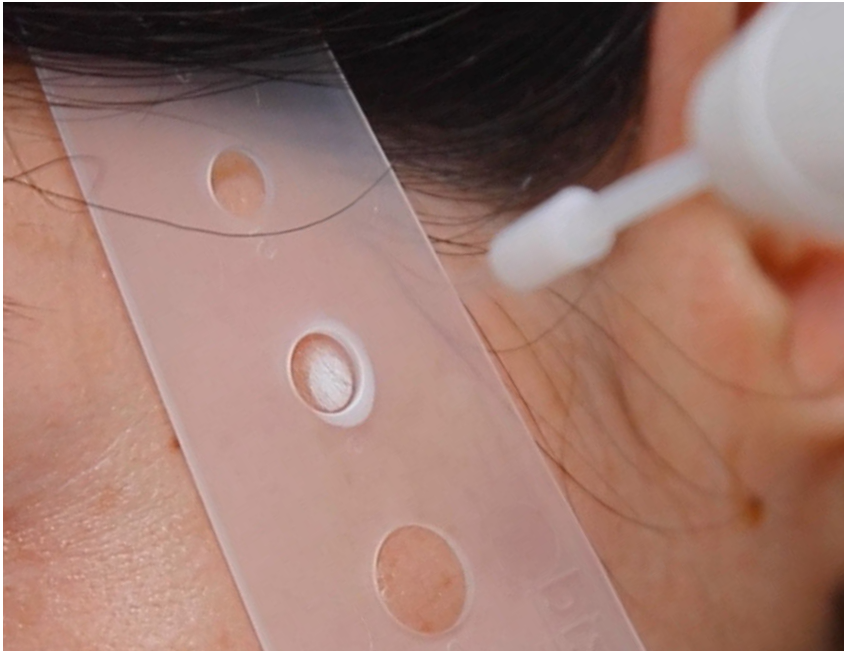
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4. Then repeat another freeze-thaw cycle. The recommended number of freeze-thaw cycles is up to 2 cycles. The total treatment time is up to 6 seconds.

The therapist assesses the patient and the treated area between each freeze-thaw cycle and must regard the treatment times as recommendations. Treatment for a longer period than recommended is associated with more frequent and more intense side effects.¹³

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Treatment of 2-4 lentigines

Solar lentigines may be individual or multifocal. In such cases, the treatment can be streamlined, as it is possible to treat 2-4 lentigines within the same period of time as it takes to treat one (up to 2 x 3 seconds).

Treatment steps using Hydrozid®

Prepare the canister and place the application template as described in treatment steps 1 and 2 in the treatment section *Treatment of one solar lentigo*.

Next treatment steps:

1. Spray at a distance of 2-3 centimetres from the first solar lentigo, for up to 3 seconds. While the ice crystals thaw and the thawing period passes, continue treating the second solar lentigo.
2. Treat the second solar lentigo using the same procedure. While the ice crystals thaw and the thawing period passes for lentigines 1 and 2, continue treating the third solar lentigo.
3. Treat the third solar lentigo using the same procedure. While the ice crystals thaw and the thawing period passes for lentigines 1, 2 and 3, continue treating the fourth solar lentigo.
4. Finish by treating the fourth solar lentigo for up to 3 seconds using the same procedure.



When the thawing period for the fourth solar lentigo has passed, the first freeze-thaw cycle is complete. Now you can start a new freeze-thaw cycle on the first solar lentigo, followed by the three others. Treat each solar lentigo with a total of up to 2 freeze-thaw cycles, equating to up to 6 seconds of treatment of each solar lentigo.

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Treatment of lentigines larger than 10 mm.

For lentigines with a diameter larger than 10 mm, follow these treatment steps:

Treatment steps using Hydrozid®

After unpacking – do not remove the tip of the application tube. It must remain in place during treatment.

1. Release the locking mechanism under the activation arm, from left to right. The canister is now ready to use.
2. Hold the canister in your dominant hand as vertically as possible. Push lightly on the canister until you hear a hissing noise and the gas is released. If you push the canister too hard, the sound will be more like when dispensing a deodorant spray, which releases unnecessary amounts of gas with a risk of damaging surrounding healthy tissue.
3. Spray at a distance of 2-3 centimetres from the centre of the change and continue by constant spraying in circular motions to the edge of the delimitation of the change. A film of white ice crystals will now form in the treated area. The treatment time of up to 3 seconds starts when ice crystals start forming on the change. The entire change must be covered by the ice crystals¹².
4. After (up to) 30 seconds, the ice crystals are no longer white, indicating that the thawing period has ended. The first freeze-thaw cycle is now completed.
5. Then repeat another freeze-thaw cycle. The recommended number of freeze-thaw cycles is up to 2 cycles. The total treatment time is up to 6 seconds.

The therapist assesses the patient and the treated area between each freeze-thaw cycle and must regard the treatment times as recommendations. Treatment for a longer period than recommended is associated with more frequent and more intense side effects.¹³



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Cryosurgery therapy may cause a stinging or burning sensation during treatment. The treated area may appear red, tender and swollen immediately after treatment.

Within 24 hours after the completion of treatment, inflammation develops in response to cell death.¹⁴ This process contributes further to destroying the change and is a natural reaction in the inflammatory phase of the wound healing process.

Wounds and possibly blisters may subsequently occur in the treated area.¹⁵ In such cases, the treated area must be protected with a plaster.

After treatment, the patient must keep the treated area clean by washing it daily with water and non-perfumed soap.

The patient should avoid exposing the treated area to sunlight for 10-14 days until the treated area is fully healed.

If repeated treatment is deemed necessary, a treatment interval of 1-2 weeks is advisable. The intensity and number of treatments depend on the patient's individual clinical response and is assessed by the therapist.

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Hydrozid® must only be used by trained healthcare professionals.

Even though the effect of short freezing times as recommended in this material does not result in scarring,¹⁵ Hydrozid® must be used with care to avoid damaging the dermis.

Exercise special caution when applying Hydrozid®:

- near cutaneous nerves, tendons and nail beds¹⁵.
- in persons with impaired arterial or venous circulation¹⁵ (e.g. diabetes patients).
- in immunosuppressed patients¹⁵.
- in persons with thin and/or sensitive skin (e.g. elderly with ageing skin, systemic scleroderma, persons treated with inhaled steroids for a prolonged period of time, etc.)¹⁵.
- in persons with dark skin types. Even though the effect of short freezing times as recommended in this material rarely results in pigmentation changes in the treated area, hypopigmentation/hyperpigmentation may occur. This change is seen in persons with dark skin types in particular.¹⁵

Do not use Hydrozid®:

- on open skin lesions or eczematous skin to avoid subcutaneous emphysema¹⁶.
- in patients with cryoglobulinemia, Raynaud's disease, cold urticaria, blood dyscrasias and Pyoderma gangrenosum¹⁵.
- in case of uncertain diagnosis of the type of lesion (biopsy for skin carcinoma)¹⁵.
- on healthy skin.

IF YOU HAVE ANY QUESTIONS OR, CONTRARY TO EXPECTATIONS, EXPERIENCE CHALLENGES WHEN USING HYDROZID®

Please contact Hydrozid® by email: info@hydrozid.eu.

Hydrozid® was developed by the Danish-owned family enterprise BIBAWO Medical A/S, Denmark, and is currently used in more than 20 countries around the world.

In Denmark, Hydrozid® is approved for the following therapeutic indications: acrochordon, actinic keratosis, cervical contact bleeding, condyloma acuminatum, gingival melanin hyperpigmentation, seborrheic keratosis, lentigo, molluscum contagiosum, verruca plana (flat warts), verruca plantaris (plantar warts), and verruca vulgaris (common warts).

Learn more about Hydrozid® on www.hydrozid.eu

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