Barrigel® – Instructions for Use

Composition

Sodium hyaluronate, stabilized	20 mg/ml
Phosphate buffered saline	q.s.

Description

Barrigel is a sterile, transparent, biodegradable gel of stabilized hyaluronic acid of non-animal origin, supplied in a glass syringe. Each syringe is terminally moist-heat sterilized in its packaging and packed in a paper carton. The product is for single use only. To ensure traceability, the package includes patient record labels that should be attached to patient records.

Intended Use

Barrigel is used to increase the distance between the prostate and the anterior rectal wall, with the intent to decrease the radiation dose delivered to the rectum when treating prostate cancer with radiation. The product should be injected into the anterior perirectal fat. The correct injection technique is important for the final result of the treatment. Before the first treatment session, contact the local Barrigel representative for more information about injection techniques and training opportunities. Barrigel shall only be administered by qualified and properly trained physicians with experience in ultrasound guidance techniques and injection techniques in the urogenital/pelvic area.

Mode of Action

Barrigel acts by adding volume to the tissue, thereby mechanically creating an increased distance between the prostate and the anterior rectal wall. The product degrades over time.

Contraindications

Barrigel is contraindicated in prostate cancer patients with clinical stage T4.

Warning

- Do not inject intravascularly. As for other injectable medical devices, inadvertent injection into blood vessels could potentially lead to vascular occlusion, distal embolisation, ischemia and necrosis.
- Do not use in patients with bleeding disorders, or in patients who are taking thrombolytics or anticoagulants such as warfarin, before consulting a specialist in hematology prior to decision about treatment.
- Do not inject if the patient is known to be allergic to hyaluronic acid based products.
- Do not resterilize Barrigel as this damages the product.
- Do not mix with other products.

Precautions

- Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent perioperative infections are to be observed.
- Knowledge of the anatomy of the treatment site and special caution are required in order to avoid perforation or compression of vessels and other vulnerable structures and organs such as prostate, rectal wall, bladder and urethra.
- Do not use where there is ongoing inflammation or infection, in or near the intended treatment site.
- Patients who are using substances that affect platelet function such as acetylsalicylic acid or non-steroidal anti-inflammatory drugs may experience, as with any injection, increased bruising or bleeding at injection sites.
- Patients with hemorrhoids should be evaluated for hemorrhoidal treatment prior to injection of Barrigel.
- For patients with immunodeficiency disorder and/or ongoing immunosuppressive therapy, a specialist in infectious diseases should be consulted prior to injection of Barrigel.
- For patients with pre-existing anorectal constrictions such as anal fissures, stenosis or other malformation, a colorectal surgeon or proctologist should be consulted prior to treatment.
- Pre-existing scar tissue, strictures, stenosis or adherences in the perirectal fat may affect the ability to inject Barrigel.
- There is no experience with injecting more than 10 ml Barrigel.
- Do not inject into the anorectal region if another injectable implant (other than Barrigel) or non-injectable implant is present.
- Injection should be stopped if excessive bleeding occurs.
- Care should be taken with the handling of the glass syringe and needle to avoid laceration or other injury.
- The device should be discarded if accidentally contaminated.
- Do not use the product if the package is damaged.
- Barrigel has not been tested in children.

Adverse Events

Anticipated procedure-related side effects are pain at the injection site and short transient injection site bleeding from the needle stick. Post-treatment anticipated side effects include mild to moderate sensation of rectal filling (leading to attempt to force defecation). Providing information to the patients that this symptom may be expected after Barrigel treatment has shown that the symptom was accepted by the patients without any attempt to force defecation.

Other adverse events that may occur after injection of Barrigel include: injection site discomfort, injection site irritation, injection site bleeding or hematoma, injection site inflammation, infection, dysuria or a weak urine stream. Injection of an excessive volume of Barrigel may cause rectal tissue tension possibly with rectal pain or discomfort and painful and/or difficult defecation, or constipation due to pressure effect. Unintentional injection leading to perforation or compression of vulnerable structures and organs such as vessels, nerves, prostate, rectal wall, bladder, urethra and urethral sphincter may cause bleeding, hematoma, prostatitis, focal rectal mucosal necrosis, urinary retention or erectile dysfunction. Inadvertent injection of vessels may cause vascular occlusion or distal embolisation. To secure correct placement of Barrigel, ultrasound guidance should be used when performing the injection.

Isolated cases of transient rectal hemorrage in the presence of concomitant hemorrhoids (onset 3 days post injection), fever (onset 5 days post injection), acute prostatitis (onset 10 days post injection) and urinary incontinence (onset 60 days post injection) have been reported.

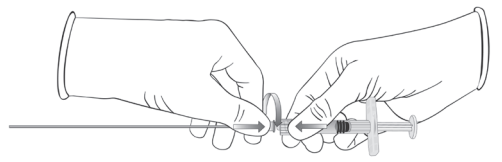
Adverse events thought to be related to the product should be reported to the Palette Life Sciences Medical Information Department.

Needle

For safe use of Barrigel, it is important to use a sterile needle, with a hub that fits the luer-lock of the syringe. It is recommended to use an 18G, or wider, needle with a length of up to 20 cm. If a thinner needle is used, the resistance during injection may be too high, resulting in an increased risk for leakage or separation of the needle from the syringe. Other needles than those recommended should be avoided.

Assembly of Needle to Syringe

Use the thumb and forefinger to hold firmly around both the glass syringe barrel and the luer-lock adapter. Grasp the needle shield with the other hand. To facilitate proper assembly, both push and rotate firmly. See picture. Strict aseptic technique must be followed. Improper assembly may result in separation of the needle and syringe during injection.



To avoid any interruption in patient treatment or the need to repeat the procedure because of leakage, or accidental contamination or damage of a syringe or needle, it is recommended that extra syringes and needles be kept in inventory.

Treatment Procedure

- The patient should be informed about the indications, precautions and potential adverse events prior to treatment.
- Aseptic technique is to be observed and antibiotic prophylaxis should be administered before injection of Barrigel.
- The injection procedure should be performed under local anaesthesia. Further anaesthesia can be provided at the discretion of the physician.
- The patient should be positioned suitably for transperineal injection.
- To avoid breakage, do not attempt to bend the needle.
- Barrigel must only be administered via an aseptic transperineal route. Do not administer transrectally.
- Before injecting, remove any air in the needle by pressing the rod carefully until a small droplet of product is visible at the tip of the needle.
- Do not apply excessive pressure to the syringe at any time. Presence of pre-existing scar tissue, strictures, stenosis or adherences in the perirectal fat may impede advancement of the needle. If resistance is encountered, the needle should be partially withdrawn and repositioned or fully withdrawn and checked for function.
- To secure correct placement of Barrigel, ultrasound guidance should be used when performing the injection. Insert the needle between the posterior prostate capsule and the anterior rectal wall, at the level of the maximum transverse diameter of the prostate. Advance the needle tip to the level of the seminal vesicles. Care should be taken to avoid perforation of the prostate capsule with the needle tip and to keep the tip as far as possible from the capsule without perforating the rectum. Aspiration prior to injection is recommended. Inject slowly into the anterior perirectal fat, while pulling the needle backwards under continuous ultrasound guidance, in order to view and verify the new space created by the injection. A volume of 3-10 mL Barrigel has been reported to create a space of ≥ 1cm. There is no experience with injecting more than 10 ml Barrigel. Multiple syringes can be used to inject the full volume of Barrigel.

- If the needle enters the rectal lumen at any time during the procedure, abandon the procedure to avoid infection.
- Stop the injection procedure if the patient experiences excessive bleeding or pain.

Do not re-shield used needles. The syringe, disposable needle and any unused material must be discarded immediately after the treatment session and must not be reused due to risk for contamination of the unused material and associated risks, including infections. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

Post-treatment Care
- The patient should be informed about the risk of infection and potential mild to moderate sensation of rectal filling and to contact the treating physician if they experience rectal bleeding, bloody diarrhea, fever, tenesmus or problems with urinating.
- The patient should be made aware that the implant might be detected during anorectal examinations and radiographic imaging of the pelvis and that future physicians should be informed that the patient had a treatment with Barrigel.

Shelf Life and Storage
The expiry date is indicated on package. Store up to 25° C. Protect from freezing and sunlight.

Legal Manufacturer
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Santa Barbara, CA 93101 USA

Sponsor in Australia
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Australia

For product information, adverse event reports, and product complaint reports, please contact:

Palette Life Sciences Medical Information Department
Phone: 1-800-794-401
Email: palettemc@dlss.com

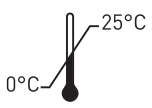
Symbols on the Packaging

Sterilized using steam or dry heat


Caution


Do not reuse


Do not use if package is damaged



Storage temperature range


Keep away from sunlight


Manufacturer

BARRIGEL®

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