Barrigel™ Patient Information Leaflet

PRODUCT NAME

Barrigel

Barrigel is a sterile, transparent, biodegradable gel of stabilised hyaluronic acid of non-animal origin, supplied in a glass syringe.

INGREDIENTS

Barrigel contains sodium hyaluronate, stabilised 20 mg/ml in a phosphate buffered saline.

INDICATIONS

Barrigel is used to increase the distance between the prostate and the anterior rectal wall, with the intent to decrease radiation dose delivered to the rectum when treating prostate cancer with radiation.

INSTRUCTIONS FOR USE

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. Barrigel should be injected into the anterior perirectal fat.

Ultrasound is used to guide proper placement of the Barrigel implant. The needle is inserted between the posterior prostate capsule and the anterior rectal wall to inject Barrigel into the anterior perirectal fat.

INTENDED PERFORMANCE

Barrigel acts by adding volume to the tissue, thereby mechanically creating an increased distance between the prostate and the anterior rectal wall. This can decrease the radiation dose delivered to the rectum during radiation therapy.

SIDE EFFECTS / UNDESIRABLE EFFECTS

Potential side effects – common:

- Pain or irritation at the injection site
- Bleeding or blood collection at the injection site
- Infection
- Painful urination or weak urinary stream
- Rectal pain or discomfort
- Constipation
- Feeling the need to have a bowel movement
- Difficulty or painful defecation

Potential side effects – rare:

- Unintentional injection into surrounding organs
- Prostatitis
- Rectal mucosal necrosis
- Erectile dysfunction
- Urinary retention
- Urinary incontinence
- Rectal haemorrhage

IF SYMPTOMS PERSIST, WORSEN OR CHANGE UNEXPECTEDLY, TALK TO YOUR HEALTHCARE PROFESSIONAL.

PRECAUTIONS

Do not have Barrigel injected if you are known to be allergic to hyaluronic acid-based products.

If you have haemorrhoids, you should be evaluated for haemorrhoidal treatment prior to injection of Barrigel.

Increased bruising or bleeding can occur at the injection site if you are using any medications that affect platelet function, like acetylsalicylic acid or non-steroidal anti-inflammatories.

You should be evaluated by a specialist prior to injection with Barrigel if you have:

- Immunodeficiency disorder or are on ongoing immunosuppressive therapy.
- Pre-existing anorectal constrictions, like anal fissures, scar tissue, stenosis, or other malformations.

EXPECTED DEVICE LIFETIME

In-Vivo Stability:

Clinically stable for 3 months but the device remains for approximately 18 months.

SERIOUS INCIDENTS

For product information, adverse event reports, and product complaints related to the use of Barrigel, contact the Palette Life Sciences Medical Information Department, the Australian Sponsor, and the Australian Therapeutic Goods Administration at the below details:

PALETTE LIFE SCIENCES MEDICAL INFORMATION DEPARTMENT

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LEGAL MANUFACTURER

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