Barrigel® Patient Information Leaflet

PRODUCT NAME Models: 011519, 011507

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

INGREDIENTS

Barrigel contains the following:
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.

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 will decrease radiation dose delivered to the rectum during radiation.

SIDE EFFECTS / UNDESIRABLE EFFECTS

Anticipated procedure-related side effects are pain at the injection site and short transient injection site bleeding from the needle stick site.
Post-treatment anticipated side effects include mild to moderate sensation of rectal filling (may lead to attempt to force defecation).

Effects associated with Barrigel injection:
Possible (rare)

- Isolated cases of transient stool (faeces) to leak unexpectedly from the rectum in the presence of concomitant haemorrhoids (a swollen vein or group of veins in the region of the anus)
- Fever
- Acute prostatitis - prostate gland becomes suddenly inflamed.
- Acute urinary incontinence - involuntary leakage of urine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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.
Do not use where there is ongoing inflammation or infection, in or near the intended treatment site.
If you have haemorrhoids, you should be evaluated for hemorrhoidal treatment prior to injection of Barrigel.

EXPECTED DEVICE LIFETIME

In-Vivo Stability**:** Persists for 12-18 months with no need for re-implantation due to a delay in radiotherapy administration or need for re-treatment.

SERIOUS INCIDENTS

For product information, adverse event reports, and product complaints related to the use of Barrigel, contact Palette Life Sciences / Teleflex, the Australian Sponsor, and the Australian Therapeutic Goods Administration (TGA) at the below details:

TELEFLEX QUALITY DEPARTMENT
Email: productcomplaints.anz@teleflex.com

AUSTRALIAN SPONSOR
Teleflex Medical Australia Pty Ltd
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AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION
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MANUFACTURER

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