

PRODUCT NAME:

This product is Princess® VOLUME Lidocaine

Each box of Princess® VOLUME Lidocaine contains 1 syringe filled with 1mL hyaluronic acid injectable gel.

DESCRIPTION:

Princess® VOLUME Lidocaine is a sterile, clear, colourless gel which contains hyaluronic acid and lidocaine (local anaesthetic) which helps improve comfort to the patient during injection.

INGREDIENTS:

Princess® VOLUME Lidocaine contains the following:

Cross-linked hyaluronic acid 23 mg/mL with 0.3% lidocaine hydrochloride. The role of lidocaine hydrochloride is to reduce the pain during treatment

INTENDED PURPOSE/INDICATION:

What is the use of Princess® VOLUME Lidocaine?

Princess® VOLUME Lidocaine is used to increase or restore volume to the face and to remodel facial contours. Princess® VOLUME Lidocaine is to be administered by a physician or health care professional.

Who can be injected with Princess® VOLUME Lidocaine?

Princess® VOLUME Lidocaine is indicated for adults (over the age of 18).

INSTRUCTIONS FOR USE:

This product is designed to be injected in the appropriate areas requiring treatment by an authorised health care professional who has had appropriate training and experience in injection techniques for volume restoration and creation. The product must be injected into non-inflamed, disinfected, healthy skin.

SIDE EFFECTS / UNDESIRABLE EFFECTS:

Anticipated procedure-related side effects are pain at the injection site.

Post-treatment anticipated possible side effects include

- Inflammatory reactions (redness, swelling, etc.) which may be associated with itching and/or pain on pressure and/or abnormal skin sensation (burning, discomfort, etc)
- Bruising (hematoma)
- Hardened mass and/or discoloration at the injection site
- Bleeding
- Hypersensitivity/allergy
- Damage to underlying tissue/structure has also been reported
- Migration of the injected product
- Vision loss due to retinal artery occlusion
- Herpes virus reactivations may be provoked in rare cases

Patients must inform their physician as soon as possible about any inflammatory reactions persisting for more than one week or any other occurring secondary effect.

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

PRECAUTIONS:

You should not use this product if:

- you tend to develop scarring, have pigment disorders or are prone to keloid formation
- you have a history of autoimmune disease or are receiving immune therapy
- you have a history of severe and/or multiple allergies. Your medical practitioner will then be able to decide on your treatment on a case-by-case basis, according to the nature of the allergy and shall also determine if you require any specific monitoring. In particular, a decision may be taken to propose skin testing for hypersensitivity or suitable preventive treatment for you prior to any injection
- you have previously received permanent fillers in the area to be treated
- you are pregnant or breastfeeding
- you are suffering inflammation or infection, in or near the intended treatment site.

Before treatment:

- Consult your doctor before injection if you are on anticoagulant therapy or receiving platelet aggregation inhibitors (e.g. acetylsalicylic acid).
- Do not use in association with laser therapy, chemical peeling, dermabrasion or mesotherapy.

After treatment:

- Do not to apply any make-up for 12 hours after the injection and avoid prolonged exposure to sunlight and UV or using saunas or Turkish baths for one week after the injection.
- Do not massage or put pressure to the treatment site for a few days following the injection,

EXPECTED DEVICE LIFETIME:

The lifetime of the implanted device has been estimated to be 9-12 months. The durability of the filling effect of the device depends on the treatment site, skin layer and injected volume.

RESIDUAL MATERIAL:

This product does not contain any manufacturing residuals that can pose a risk to patients.

SERIOUS INCIDENTS/CONTACT:

Related to the use of Princess® VOLUME Lidocaine, contact the Manufacturer, Australian Sponsor and the Therapeutic Goods Administration at the below details:

AUSTRALIAN SPONSOR

CROMA Australia Pty Ltd.
Level 26, 1 Bligh Street
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AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

www.tga.gov.au

MANUFACTURER

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