Hyaluxelle®

Patient Information Leaflet

THE ART OF FEELING

LET INNOVATION AWAKEN WHAT THE BODY HAS SILENCED

Next generation hyaluronic acid designed to relieve vulvovaginal symptoms associated with genitourinary syndrome of menopause (GSM)

IBSA

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This leaflet is for patients and provides information about a Hyaluxelle procedure to treat genital and sexual symptoms of genitourinary syndrome of menopause (GSM).

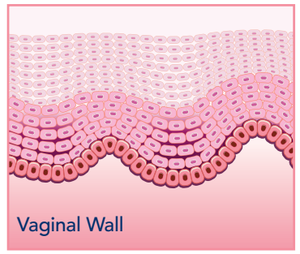
What is GSM?

GSM is a collection of symptoms affecting the female pelvic and reproductive organs caused by low oestrogen. This may be caused by natural menopause, premature ovarian insufficiency or medical treatments (such as surgical removal of ovaries, chemotherapy and radiotherapy treatments). Low oestrogen contributes to thinning of the vaginal walls, reduction in tissue elasticity and reduction in natural lubrication [1,2].

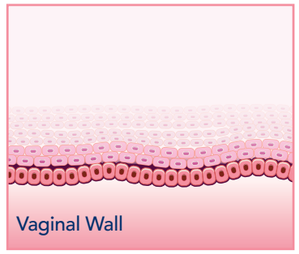
What are the symptoms of GSM?

Symptoms include:

1. Vaginal dryness (sexual dysfunction)
2. Pain during sexual intercourse (sexual dysfunction)
3. Burning (genital symptoms)
4. Itching (genital symptoms)
5. Altered vaginal pH and vaginal infections (thrush, bacterial vaginosis)
6. Urinary urgency (urinary)
7. Urinary frequency (urinary)
8. Urinary tract infections (urinary) [1,2]



Normal:
Thick and moist vaginal lining



Atrophy:
Thin and dry vaginal lining

How common is GSM?

Whilst up to 70% of menopausal women will experience symptoms of GSM, only 7% receive treatment, meaning women are suffering in silence [1]. Symptoms are often attributed to normal ageing and therefore left unreported and untreated. Symptoms often lead to reduced sexual activity, which impacts quality of life for both women and their partners [2].

How is it diagnosed?

Your clinician may ask you questions about your symptoms, lifestyle and sexual history and conduct a physical examination. Laboratory tests are not generally needed to make a GSM diagnosis. GSM symptoms may be attributed to other conditions such as vaginal or urinary infection, so it is crucial your clinician obtains a thorough history and examination to distinguish GSM from other conditions [1].

How can Hyaluxelle help?

Designed to be compatible with our body's natural hyaluronic acid [7], Hyaluxelle restores the natural environment of vulvovaginal tissues, by:

1. Increasing tissue thickness, [3,4]
2. Increasing tissue hydration, [7]
3. Reducing inflammatory cells [3,4]
4. Improving blood flow to the area [3,4]

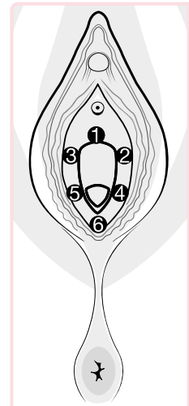
This may lead to reduction in painful genital symptoms such as burning, itching and discomfort, reduced pain during sexual penetration, improved sexual function and a better quality of life for women [5].

What is Hyaluxelle?

Hyaluxelle is a high and low molecular weight hyaluronic acid injection designed to stimulate atrophic tissues. It is a medical device licensed to treat vaginal dryness, pain during sexual intercourse, genital burning and itching (non-infectious) related to vulvovaginal atrophy [7].

Where is the injection administered?

All woman's vaginal tissues are individual. Your clinician will decide based on your history and examination where to administer the injection to treat your specific symptoms. The injections are delivered into the vulvovaginal tissues using a very small needle. Your clinician may ask you to apply anaesthetic cream to the area prior to the injections. Only trained clinicians can administer Hyaluxelle injections.



① Anterior commissure: 0.3 mL
② Anterior right lateral: 0.3 mL
③ Anterior left lateral: 0.3 mL
④ Posterior right lateral: 0.3 mL
⑤ Posterior left lateral: 0.3 mL
⑥ Posterior commissure: 0.5 mL

Apply a light massage at the injection sites.

This technique allows homogeneous distribution of the product in the vestibule area [1]

How many injections of Hyaluxelle will I need?

There are two treatments, spaced 30 days apart [7].

Are there any risks/side effects?

Hyaluxelle is well tolerated with no known long-term risks or interactions [5,7]. Injections should be performed on healthy skin. Hyaluxelle may cause temporary local side effects including [7]:

- Sensation of heat
- Slight bruising
- Redness
- Itching at injection site
- Temporary pain or swelling at injection site
- Oedema
- Ecchymosis
- Erythema
- Bruising
- Temporary pain and/or swelling

These side effects can be relieved by applying ice on the treated area. They generally disappear after a short period of time.

If you experience undesirable effects during or after your treatment, you must inform your clinician.

You should not have Hyaluxelle if:

- Are pregnant or breast feeding
- Have an autoimmune disease
- Have a collagen disorder (for example Ehler's Danlos) [7]
- Have known hypersensitivity or allergies to the components or product

What should I avoid after the injection?

- You should avoid a sauna or a Turkish bath and sports such as cycling or horse riding and sexual intercourse in the 3 days following the treatment
- You should avoid sun exposure, or exposure to UV rays for 3-5 days after injection [7]

GSM over time

It is important to consider your symptoms and discuss these with your health care professional when deciding which treatment is best for you. GSM unlike other menopause symptoms may not improve spontaneously but usually progresses over time [1].

Where can I get more information about Hyaluxelle?
Scan the QR code or visit: www.ibsaurogyn.com

IBSA VITAMINS:

Maintaining your levels of important supplements is important to recovery and can be done through a balanced diet. But if you need additional support, IBSAs innovative technology makes talking supplements easy.

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Small and lightweight films ready to take anytime, anywhere.

Precise

Consistent vitamin dosages in each film.

Our convenient, thin-film vitamins melt on your tongue quickly without the need for water.

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References

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7. Hyaluxelle Instructions for use

To access the Hyaluxelle IFU, please scan the QR code

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