

HYDRO GYN- calendula officianalis, olive extract gel
Shenzhen water element e-commerce Co., LTD

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

85964-001-01

Active ingredients

Calendula Offcianalis 3X PHUS
Olive Extract (Oleuropein) 3X HPUS

Purpose

Moisturizing and Healing Agent
Antimicrobial and Healing Agent

Uses

HydroGYN Vaginal Moisturizer is formulated to address symptoms associated with estrogen deficiency during menopause, perimenopause, or other vaginal changes that contribute to vaginal atrophy. It is specifically designed to provide relief from vaginal dryness, irritation, and discomfort caused by thinning and inflammation of the vaginal walls (atrophic vaginitis). By restoring and maintaining optimal vaginal moisture levels, this product helps support the natural vaginal microbiome and may assist in reducing the risk of urinary tract infections associated with vaginal atrophy. It is also suitable for managing symptoms related to menopause, perimenopause, postpartum recovery, or conditions requiring enhanced vaginal hydration.

Warnings

- For vaginal use only.
- Do not use this product if you have a known allergy to any of its ingredients.
- Consult your healthcare provider before use if you are pregnant, breastfeeding, or undergoing treatment for a vaginal infection.
- Do not use this product if the seal is broken or missing.
- In case of accidental ingestion, seek medical assistance or contact a Poison Control Center immediately.

When using this product

- Administer only as directed. Avoid exceeding the recommended application frequency.
- To prevent potential desensitization or tolerance, do not use the product more than once within a 48 - hour period unless otherwise advised by a healthcare professional.
- Before using this product with other therapeutic products such as douches,

spermicides, or antifungal treatments, seek medical guidance to avoid interactions or diminished therapeutic efficacy.

- Mild vaginal sensations, including burning, itching, or irritation, may occur initially. Should these symptoms persist, intensify, or be accompanied by abnormal discharge, bleeding, or systemic symptoms (e.g., fever, chills), discontinue use and consult a healthcare provider promptly.
- Do not reuse or share the applicator to minimize the risk of contamination or infection. Dispose of the applicator after a single use.

Stop Use and Consult a Healthcare Provider If

- Symptoms do not improve after 3 applications or worsen during use.
- You experience severe vaginal irritation, abnormal discharge, or unexpected bleeding.
- Systemic symptoms such as fever, chills, or abdominal pain occur.
- Premenopausal women experience any of the above - mentioned symptoms.

If Pregnant or Breastfeeding

Consult a healthcare provider before using this product to ensure its safety and suitability during pregnancy or lactation.

keep out of reach of children

This product is intended for adult use only. In case of accidental ingestion by a child, seek immediate medical attention or contact a Poison Control Center.

Other information

- Do not use this product if the sealed packaging is compromised, damaged, or previously opened.
- Store at a controlled temperature of 20°C to 25°C (68°F to 77°F).
- Protect the product from direct sunlight as excessive ultraviolet (UV) rays may degrade the product stability.
- Temporary deviations outside this range are acceptable but should be minimized to preserve product and effectiveness of the homeopathic ingredients.
- If the product is frozen, thaw it before use.
- Always store the product in a dark, cool, and dry location.

Directions

Preparation:

Place a sanitary panty liner in your underwear to prevent any potential leakage. Carefully open the sealed foil pouch and remove the pre - filled applicator. Do not tamper with the applicator tip until ready for use.

Positioning:

Recline in a comfortable position on your back with your knees bent to facilitate insertion.

Alternatively, you may stand or sit, based on your preference and comfort.

Application:

Gently insert the thin end of the applicator into the vaginal opening until comfortable. Firmly press the thick end of the applicator to dispense the product completely into the vaginal canal.

Post - Application:

Remove and discard the applicator immediately after use. Do not attempt to reuse. Be aware that a slight increase in vaginal burning, itching, or irritation may occur temporarily as your body adjusts to the product.

If these symptoms persist or worsen, consult a healthcare provider.

Ensure to follow these instructions carefully for optimal results and safety.

Inactive ingredients

Purified water, Hyaluronic Acid 0.05%, Tocopherol Acetate (Vitamin E), Carbomer, Carbomer, Sodium Hyaluron Hydroxide, Sodium Edetate, Hop extract, Organic Olive Oil, Organic Avocado Oil, Olive Fruit Viliin Extract, Taraxacum Mongolicum Extract

85964-001-01

LASTS UP TO 3 DAYS

Estrogen
Free

Hydro
GYN

— LONG-LASTING —
vaginal moisturizer

With Hyaluronic Acid

10 Pre-filled single-use
Applicators

Drug Facts

Active ingredients	Purpose
Calendula Officinalis 3X PHUS	Moisturizing and Healing Agent
Olive Extract (Oleuropein) 3X HPUS	Antimicrobial and Healing Agent

Uses
HydroGYN Vaginal Moisturizer is formulated to address symptoms associated with estrogen deficiency during menopause, perimenopause, or other hormonal changes that contribute to vaginal atrophy. It is specifically designed to provide relief from vaginal dryness, irritation, and discomfort caused by thinning and inflammation of the vaginal walls (atrophic vaginitis). By restoring and maintaining optimal vaginal moisture levels, this product supports the integrity of the vaginal epithelium, enhances elasticity, and improves overall vaginal health. HydroGYN is ideal for managing symptoms related to menopause, perimenopause, postpartum recovery, or conditions requiring enhanced vaginal hydration.

Warnings

- For vaginal use only.
- Do not use this product if you have a known allergy to any of its ingredients.
- Consult your healthcare provider before use if you are pregnant, breastfeeding, or undergoing treatment for a vaginal infection.
- Keep out of reach of children.
- In case of accidental ingestion, seek medical assistance or contact a Poison Control Center immediately.

When Using This Product

- Administer only as directed. Avoid exceeding the recommended application frequency.
- To prevent potential desensitization or tolerance, do not use the product more than once within a 48-hour period unless otherwise advised by a healthcare professional.
- If concurrently using other intravaginal products such as douches, spermicides, or antifungal treatments, seek medical guidance to avoid interactions or diminished therapeutic efficacy.
- Mild vaginal sensations, including burning, itching, or irritation, may occur initially. Should these symptoms persist, intensify, or be accompanied by abnormal discharge, bleeding, or systemic symptoms (e.g., fever, chills), discontinue use and consult a healthcare provider promptly.
- Avoid ocular contact. If accidental contact occurs, irrigate the eyes thoroughly with water.
- Do not reuse or share the applicator to minimize the risk of contamination or infection. Dispose of the applicator after a single use.

Stop Use and Consult a Healthcare Provider If:

- Symptoms do not improve after 3 applications or worsen during use.
- You experience severe vaginal irritation, abnormal discharge, or unexpected bleeding.
- Systemic symptoms such as fever, chills, or abdominal pain occur.

Seek immediate medical attention for severe or persistent symptoms.

If Pregnant or Breastfeeding
Consult a healthcare provider before using this product to ensure its safety and suitability during pregnancy or lactation.

Keep Out of Reach of Children
This product is intended for adult use only. In case of accidental ingestion by a child, seek immediate medical attention or contact a Poison Control Center.

Directions for Use

- 1.Preparation:**
 - Place a sanitary panty liner in your underwear to prevent any potential leakage.
 - Carefully open the sealed foil pouch and remove the pre-filled applicator. Do not tamper with the applicator tip until ready for use.
- 2.Positioning:**
 - Recline in a comfortable position on your back with your knees bent to facilitate insertion.
 - Alternatively, you may stand or sit, based on your preference and comfort.
- 3.Application:**
 - Gently insert the thin end of the applicator into the vaginal opening until comfortable.
 - Firmly press the thick end of the applicator to dispense the product completely into the vaginal canal.
- 4.Post-Application:**
 - Remove and discard the applicator immediately after use. Do not attempt to reuse.
 - Be aware that a slight increase in vaginal burning, itching, or irritation may occur temporarily as your body adjusts to the product.

If these symptoms persist or worsen, consult a healthcare provider.
Ensure to follow these instructions carefully for optimal results and safety.

Other information

- Do not use this product if the sealed packaging is compromised, damaged, or previously opened.
- Store at a controlled temperature of 20°C to 25°C (68°F to 77°F)
- Temporary deviations outside this range are acceptable but should be minimized to preserve product stability.
- Protect the product from direct sunlight as exposure to ultraviolet (UV) rays can degrade the potency and effectiveness of the homeopathic active ingredients. Prolonged exposure to sunlight may alter the chemical stability and reduce the therapeutic efficacy of the formulation. Always store the product in a dark, cool, and dry location.
- If the gel exhibits liquefaction due to elevated temperatures, refrigerate for 10 minutes to restore its intended viscosity prior to application.
- This product is designed for single-use only. Discard the applicator immediately after application to prevent contamination.
- For optimal results, complete symptom relief may require consistent usage of one application every 3 days for a period of 30 days
- Follow the recommended regimen unless otherwise advised by a healthcare provider.
- Avoid contact with sharp objects or surfaces that could puncture the applicator or compromise the integrity of the product.

Inactive ingredients
Purified water, Hyaluronic Acid 0.05%, Tocopherol Acetate (Vitamin E), Carbomer, Carbomber, Sodium Hydium Hydroxide, Sodium Edetate, Hop extract, Organic Olive Oil, Organic Avocado Oil, Fructus Chidii Extract, Taraxacum Mongolicum Extract.

HYDRO GYN

calendula officinalis, olive extract gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85964-001
Route of Administration	CUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	3 [hp_X] in 1 mL
OLEUROPEIN (UNII: 2O4553545L) (OLEUROPEIN - UNII:2O4553545L)	OLEUROPEIN	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CNIDIUM MONNIERI FRUIT (UNII: V1A3S3CUS)	
TARAXACUM MONGOLICUM (UNII: 4E8QL88U6H)	
HOPS (UNII: 01G73H6H83)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
SODIUM HYALURONATE (UNII: YSE9PPT4TH)	
CARBOMER (UNII: 0A5MM307FC)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HYALURONIC ACID (UNII: S270N0TRQY)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85964-001-01	10 in 1 BOX	08/08/2025	
1		10 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		08/08/2025	

Labeler - Shenzhen water element e-commerce Co., LTD (976726806)

Registrant - Shenzhen water element e-commerce Co., LTD (976726806)

Establishment

Name	Address	ID/FEI	Business Operations
Shenzhen water element e-commerce Co., LTD		976726806	manufacture(85964-001)

Revised: 8/2025

Shenzhen water element e-commerce Co., LTD