1.6 PRODUCT INFORMATION

1.6.1 SPC – Summary of the Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

LACTIV (Vaginal Wash)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Lactic Acid BP	1.2 % w/v
Liquid Sorbitol (Non-Crystallising) BP	1.0 % w/v
Tea Tree Oil (Melaleuca Alternifolia)	0.05 % w/v
Hippophae Rhamnoides (Sea Buckthorn) fruit oil	0.25 % w/v
Cocamidopropyl Betaine	7.0 % w/v
Polyquaternium-7	0.5 % w/v
D-Panthenol USP	0.5 % w/v
Excipients	qs

3. PHARMACEUTICAL FORM

Vaginal Wash

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

LACTIV (Vaginal Wash) has an antiseptic and moisturizing action to restore the normal vulval pH even in the presence of infection and render the vulva and perineum symptom free. **LACTIV** (Vaginal Wash) act as a perineal wash as they provide an acidic pH and maintain the moisture of the perineal area, improving barrier function.
LACTIV (Vaginal Wash) improves hydration, relief of external genital itching and irritation common during excessive secretions, menstruation, pregnancy and menopause. As an external genital wash for prompt healing of repaired cut after childbirth and protection before and after sexual intercourse. As an itch reliever for common external irritation due to infections

4.2 Posology and method of administration

Vaginal wash
Pour a small amount on your hand, apply externally to intimate areas and rinse with water. For everyday use or as directed by the physician. To always feel fresh, use regularly especially during the menstrual period. In case of vaginal infection use daily to supplement the treatment prescribed.

Mode of administration
Vaginal wash

4.3 Contraindications
Contraindicated in patients with known hypersensitivity to the drug or any ingredient in the formulation.

4.4 Special warnings and special precautions for use
LACTIV is for external use only; do not use in eyes, ears, or mouth. Use with caution on mucous membranes and apply on infected surfaces at the lowest bactericidal concentration to decrease the risk of anaphylactic reactions. Possible irreversible corneal damage after accidental ocular exposure. Do not touch eyes with hands. If ocular contact occurs, rinse eye promptly and thoroughly with water. Serious,systemic hypersensitivity reactions, including hypotension, tachycardia, shortness of breath, skin erythema, and anaphylaxis, have been reported with preparations applied topically to the skin. **LACTIV** is normally well tolerated by people, but may cause irritation or sensitizing in some individuals. Use only as indicated. If itching persists or if pregnant, consult a doctor.

4.5 Interaction with other medicinal products and other forms of Interaction
No drug interaction was found

4.6 Pregnancy and lactation
Pregnancy
Category B.

Lactation
Unlikely to be distributed into human milk following topical or intravaginal application.

4.7 Effects on ability to drive and use machines
None

4.8 Undesirable effects
Skin irritation, itching, or redness. Severe allergic reactions rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue.

4.9 Overdose
None

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

General Properties

Pharmacotherapeutic Group:

LACTIV (Vaginal Wash) protects women from common microorganism that can cause feminine itching and common genital infections. It is nontoxic and nonirritating.

Pharmacotherapeutic group: Antiinfectives , antiseptics and moisturizer

ATC Code:

Lactic Acid BP : G01AD01
Liquid Sorbitol BP : A06AD18,A06AG07, B05CX02 and V04CC01
D-Panthenol USP : D03AX03
Cocamidopropyl Betaine : -----
Polyquaternium-7 : -----
Tea Tree Oil (Melaleuca Alternifolia) : -----
Sea Buckthorn (Hippophae Rhamnoides) fruit oil : -----

Mechanism of action:

LACTIV improves the patient's condition by performing the following functions:

- Inhibiting the growth of bacteria.
- Inhibiting the growth of fungi.

5.2 Pharmacokinetic properties

5.2.1 Pharmacokinetics Property:

Absorption

Bioavailability

Poorly absorbed from GI tract or percutaneously following topical application to skin. Low concentrations appear to be absorbed systemically following intravaginal administration. Adsorbed onto outer layers of skin following topical application to intact skin, resulting in a persistent (residual) antimicrobial effect. In pregnant women who received a 2% solution intravaginally as a vaginal wash during labor, concentrations ranging from 0.01–0.083 mcg/mL were detected in the blood (limits of detection 0.01 mcg/mL) of approximately 33% of these women.

Special Populations

Possible systemic absorption when topical preparations used as skin cleansers in neonates or infants.

Distribution

Not known whether crosses the placenta or is distributed into milk.

Elimination

If absorbed percutaneously following topical application to the skin, appears to be mainly excreted unchanged in feces.

10.5.3 Preclinical Safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sr.No.	Raw materials	Pharmacopoeia
1.	Plantacare 818 UP (Coco-Glucoside)	IHS
2.	Galaxy 226	IHS
3.	Lamesoft PO65 (Coco-Glucoside & Glyceryl Oleate)	IHS
4.	Sodium lauryl sulfate	BP
5.	Lactose	BP
6.	Imidurea (Germall 115)	USP
7.	Hydroxyethylcellulose	BP
8.	Euperlan PK 771	IHS
9.	Glycerol	BP
10.	Polyoxyl 40 Hydrogenated Castor Oil (Creshmer RH 40)	USP
11.	Purified water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 30°C in a dry & dark place. Do not freeze.

6.5 Nature and contents of container

200 ml filled in HDPE bottle packed in carton.

6.6 Instructions for use and handling

No special requirements

7. Marketing Authorisation Holder

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8. Marketing Authorisation Number (S)

Form 28, KD/258

9. Date of First Authorisation/Renewal of the Authorisation

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10. Date of Revision of the Text
