

LACTIV
(Vaginal Wash)
Module 1



1.6.3 Patient information leaflet (PIL)

1. Name of Product

LACTIV (Vaginal Wash)

2. Description of Product

A white to pearly sheen coloured liquid.

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet,
- please tell your doctor or pharmacist.

In this leaflet:

1. What **LACTIV** is and what it is used for
2. Before you use **LACTIV**
3. How to use **LACTIV**
4. Possible side effects
5. How to store **LACTIV**
6. Further information

1. WHAT LACTIV IS AND WHAT IT IS USED FOR

LACTIV (Vaginal wash) has an antiinfective, 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.

2. BEFORE YOU USE LACTIV (Vaginal Wash)

Do not use LACTIV (Vaginal wash) **if you are:**

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

- **Take special care with LACTIV** (Vaginal wash)

LACTIV (Vaginal wash) 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

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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** (Vaginal wash) 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.

Pregnancy and breast-feeding

Pregnancy

Category B.

Lactation

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

3. HOW TO USE LACTIV (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.

4. POSSIBLE SIDE 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.

5. HOW TO STORE LACTIV (Vaginal wash)

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

Keep out of reach of children.

6 FURTHER INFORMATION

What LACTIV (Vaginal wash) **contains**

The active substances are Lactic Acid BP, Liquid Sorbitol (Non-Crystallising) BP, Tea Tree Oil (Melaleuca Alternifolia), Hippophae Rhamnoides (Sea Buckthorn) fruit oil, Cocamidopropyl Betaine, Polyquaternium-7, D-Panthenol USP.

Excipients used in the formulation of **LACTIV** (Vaginal wash) are Plantacare 818 UP (Coco-Glucoside), Galaxy 226, Lamesoft PO65 (Coco-Glucoside & Glyceryl Oleate), Sodium Lauryl Sulfate BP, Lactose BP, Imidurea (Germall 115) USP, Hydroxyethylcellulose BP, Euperlan PK 771 IHS, Glycerol BP, Polyoxyl 40 Hydrogenated Castor Oil (Creshmer RH 40) USP & Purified water BP

What LACTIV (Vaginal wash) **like**

LACTIV (Vaginal wash) is A white to pearly sheen coloured liquid.

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7 Marketing Authorisation Holder and Manufacturer:

Name and Address of Manufacturer

Aurochem Laboratories (India) Pvt. Ltd.

8, Palghar Taluka,

Industrial Co.-op. Estate Ltd.

Palghar – 401 404,

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Name and Address of Marketing Authorisation Holder

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8 Date of Revision of PIL
