

## Birch Triterpenes

**Regulations:** Filsuvez (R) topical gel has been successfully registered for Epidermolysis bullosa treatment in the United States of America (USA), a significant milestone in dermatology.

### General Information:

**Registered Company:** Chiesi Global Rare Diseases.

**Regulatory Status:** R.X.

**Mechanism of Action:** unknown regarding treatment of Epidermolysis bullosa

### Indication:

**Approved (Labeled) indication:** Epidermolysis bullosa.

**Route of Administration:** topical.

**Dosage Forms:** topical gel.

**Dosing/Administration:** Apply a 1 mm layer of Filsuvez (R) topical gel topically to the affected wound surface once daily and cover it with a sterile, non-adhesive dressing.

**In the specific population, a dose adjustment in renal/hepatic failure/geriatrics is required.** No dosage adjustment is needed.

**Pharmacokinetic:**

### Metabolism

- Hepatic.

### Safety:

**Common Adverse Reactions (%):** Site reactions may occur.

**Drug Interactions:** Not determined.

**Contraindications:** Not determined.

**Precautions:** Skin reactions and local hypersensitivity may occur.

**Monitoring Requirements:** Still being determined.

**Sound-Alikes/ Look-Alikes:** Not available.

**High Alert:** Not available.

**Boxed warnings or alerts issue:** Not available.

**Toxicity if antidote required:** Not available.

**Storage if there is a particular condition:** Store at a controlled room temperature between (20 -25°C).

### Patient counseling

Avoid eye contact or mucous membranes, and rinse thoroughly with water if contact occurs.

### Cost Analysis

Drugs	Drug classes	Approval Indication	Dose	Cost (American Dollar)	Insurance drug formulary(SCHI)
Birch triterpenes	Wound care agent	Epidermolysis bullosa	1 mm	list price is £275.33 per 23.4g tube	Not Covered

### REFERENCE

1. Product Information: FILSUIVEZ (R) topical gel, birch triterpenes topical gel. Chiesi USA, Inc. (Per Manufacturer), Cary, NC, 2023.

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