

## **ECHINACIN Madaus Ointment** *Madaus GmbH*

### **1. Name of pharmaceutical product**

Echinacin® Madaus Ointment

*Active ingredient:* pressed juice from fresh flowering purple coneflower herb

### **2. Prescription status**

Available in pharmacies only.

### **3. Composition of product**

#### **3.1 Drug category or group of indication**

Plant-based remedy for the treatment of wounds

#### **3.2 Nature of ingredients and nature and quantity of pharmacologically active ingredients**

100 g ointment contains:

- pharmacologically active ingredients: pressed juice from fresh flowering purple coneflower herb [1.7 - 2.5: 1] 16 g
- preservative: methyl-4-hydroxybenzoate
- other ingredients: purified water, liquid paraffin, yellow petroleum jelly, microcrystalline wax, ethanol, propylene glycol, (glycerol, sorbitan) (oleate, stearate), polyethylene glycol-45/dodecyl-glycol copolymer, (Mr 4000), wool wax alcohols, magnesium sulphate heptahydrate.

### **4. Uses**

Poorly healing superficial wounds.

### **5. Contraindications**

Hypersensitivity to the active ingredient or to any of the adjuvants, e.g. methyl 4-hydroxy-benzoate (parabens) or to composites.

### **6. Side effects**

Hypersensitivity reactions may occur in occasional instances. Local allergic reactions (inflammations of the skin) have been reported.

### **7. Interactions with other drugs**

None known

### **8. Warnings**

Not applicable

### **9. Principal incompatibilities**

None known

### **10. Dosage, including single and daily doses**

Unless otherwise directed, adults should apply a strip of the ointment 1-2 cm in length 2-3 times daily and spread it thinly and uniformly over the skin.

Children between 6 and 12 years of age should have a strip of ointment 0.5-1.5 cm in length applied 2-3 times daily. Children between 2 and 5 years of age should have a strip of ointment 0.5-1 cm in length applied 2-3 times daily. In all cases the ointment should be spread thinly and uniformly over the skin.

### **11. Mode and duration of use**

Apply the ointment to the affected skin area or to the dressing.

The ointment should not be used without interruption for longer than 8 weeks.

### **12. Signs and symptoms of overdosage, emergency measures and antidotes**

Not applicable

### **13. Pharmacological and toxicological properties, pharmacokinetics and bioavailability, insofar as this information is necessary for therapeutic use**

#### **13.1 Pharmacological properties**

A direct inhibitory action on hyaluronidase, either of tissue origin or formed by pathogenic microorganisms, with consequent stabilisation of the hyaluronic acid present in the cement substances; activation of fibroblasts; this tends to promote their differentiation into fibrocytes, and these cells in turn produce hyaluronic acid.

Activation of phagocytes originating both from the tissues and from the blood (histiocytes, leucocytes). Operating by phagocytosis or extracellular degradation, these cells then act upon pathogens or breakdown products and render them harmless.

## 13.2 Toxicological properties

Echinacin® Madaus Ointment has shown good local tolerance after repeated cutaneous application to experimental animals.

Tests for genotoxicity carried out on microorganisms, mammalian cells *in vitro* and mice provided negative results.

## 14. Other information

Not applicable.

## 15. Shelf-life

4 years

## 16. Special recommendations for storage

None

## 17. Presentation and pack sizes

Original packs containing 25 g [N1] and 50 g [N2] of ointment