SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

HAMAZINC 5.35% + 18% cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains:

Active substance:

Hamamelis virginiana distillate	53.5 mg
Zinc oxide	180 mg

Excipients:

Monopropylene glycol	0.45 mg
Cetostearyl alcohol	35 mg

See Section 6.1 for excipients.

3. PHARMACEUTICAL FORM

Cream
White or off-white, homogenous-looking cream

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

HAMAZINC cream is recommended to use in the following indications:

- Diaper rash in babies and young children
- Maintenance treatment for diaper rash aggravating due to fungal infections or bacterial infections
- First and second degree burns / sun (UV) burns
- Superficial skin lesions such as scratches and cuts
- Care and prevention of cracked nipples in nursing mothers
- Care and protection of dry, cracked, split skin (including skin of elderly and diabetics)
- Adjuvant treatment in flowing lesions such as exudative eczema, intertrigo and in acute sores such as leg ulcer and decubitus ulcers

4.2. Posology and method of administration

Posology/ frequency and duration of administration:

HAMAZINC is applied few times a day to the lesion area.
There is no time limitation to using HAMAZINC.

Method of administration

HAMAZINC is applied to the lesion area as a thin layer.
Lesion area can be covered with gauze bandage following application, if necessary.
For nipple care of nursing mothers, HAMAZINC is applied to the nipples after each breastfeeding.

Additional information on special populations:

Renal/Hepatic failure

There are no studies on topical HAMAZINC used in renal or hepatic failure.

Pediatric population

It is recommended to use according to doctor's advice in infants and children under 6 years of age (if to be used on wide skin area).

Geriatric population

Not reported.

4.3. Contraindications

HAMAZINC has no known contraindications.
However, as a general measure, it should not be used in subjects who have hypersensitivity to any of the active substances or excipients in its composition.

4.4. Special warnings and precautions for use

Contact of HAMAZINC with eyes should be avoided. In case of contact with eyes, eyes should be washed with plenty of water.

If patient's current complaints persist or worsen, a doctor should be consulted.

It may cause skin irritation due to monopropylene glycol content.

Local skin reactions (e.g., contact dermatitis) may occur due to cetostearyl alcohol content.

4.5. Interactions with other medicinal products and other forms of interaction

No interaction was reported.

Additional information on special populations:

Interaction studies of special populations were not conducted.

Pediatric population:

Interaction studies of pediatric populations were not conducted.

4.6. Pregnancy and lactation
General recommendation
Pregnancy category was not reported.

Women of childbearing potential/Birth control (Contraception)
Not reported.

Pregnancy
For Hamamelis virginiana no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to fetal development. Caution should be exercised when prescribing to pregnant women.

Lactation
It is not known whether Hamamelis virginiana is excreted in human milk. Excretion of Hamamelis virginiana in milk was also not investigated in animals. In deciding whether to stop breastfeeding or to stop HAMAZINC treatment, benefits of breastfeeding for the infant and benefits of HAMAZINC for the nursing mother should be considered.

Reproductive ability/Fertility
Not reported

4.7. Effects on ability to drive and use machines

No undesirable effects on the ability to drive and use machines were reported.

4.8. Undesirable Effects
Adverse drug reactions are reported by the frequencies below:
Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1000 to < 1/100); rare (≥ 1/10000 to < 1/1000); very rare (< 1/10.000); unknown (cannot be estimated by available data)

Immune system disorders:
Unknown: Allergic reaction

Skin and subcutaneous tissue disorders:
Uncommon: Exanthema, skin irritation, pruritus, burning and stinging sensation, erythema, dry skin.
Unknown: Contact dermatitis (eczema), urticarial, angioneurotic edema.

4.9. Overdose and management
There is no information indicating a potential for overdose with local administration of HAMAZINC.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Other Dermatologicals
ATC Code: D11AX
The *Hamamelis virginiana* aquaeous extract present in HAMAZINC composition has astringent, local hemostatic and anti-inflammatory activities.
Following skin injuries, the astringent effect provides tissue constricting and thickening by causing coagulation of proteins at the injury site.
The local hemostatic effect reduces bleeding time and accelerates clotting at the injury site following a skin injury.
It relieves signs and symptoms of inflammation of the skin with its anti-inflammatory activity.
Zinc oxide accelerates wound healing and epithelization.

5.2. Pharmacokinetic properties

General characteristics

Absorption

HAMAZINC is an aquaeous fat emulsion (contains 12% fat).
It was reported that liposomes present in the preparation enable absorption by the skin and reduce transepidermal loss of moisture. There is no information indicating systemic effects.

Distribution:

Not reported.

Biotransformation:

Not reported.

Elimination:

Zinc oxide: It is not absorbed in clinically significant amounts through intact skin and mucosa.

5.3. Preclinical safety data

Not reported.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Citric acid monohydrate
Disodium EDTA
Cetomagrogol 1000
Monopropylene glycol
Cetostearyl alcohol
Liquid paraffin
White paraffin
Purified water

6.2. Incompatibilities
Not reported.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature under 25°C.

6.5. Nature and contents of container
It is presented in HDPE capped aluminum tubes of 30 gr, 60 gr and 90 gr.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling
Unused products or waste materials must be discarded in accordance with the "Regulation on control of the medical waste" and "Regulations on control of the packaging wastes".

7. MARKETING AUTHORISATION HOLDER
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8. MARKETING AUTHORISATION NUMBER
2014/850

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:
Date of first authorization date: 27.11.2014
Date of authorization renewal:

10. DATE OF REVISION OF THE TEXT
28.05.2018