

## PATIENT INFORMATION LEAFLET

### HAMAZINC 5.35% + 18% cream

#### For external use only.

- **Active substances:** Each 1 gram cream contains 53.5 mg hamamelis virginiana distillate and 180 mg zinc oxide.
- **Excipients:** Methyl paraben (E218), ethyl paraben (E214), propyl paraben (E216), cetomagrogol 1000, propylene glycol, cetostearyl alcohol, liquid paraffin, white paraffin and deionized water.

**Read this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine because it contains important information for you.**

This medicine is available without prescription for you to treat minor disorders without a doctor's help, with the recommendation of your pharmacist. However, you still need to use HAMAZINC carefully to get the best results from it.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only, do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher** or **lower** doses than the dose which was recommended for you.*

#### **What is in this leaflet:**

- 1. What HAMAZINC is and what is it used for?***
- 2. Before you use HAMAZINC***
- 3. How to use HAMAZINC?***
- 4. Possible side effects***
- 5. How to store HAMAZINC?***

#### **1. What HAMAZINC is and what is it used for?**

- HAMAZINC is a white appearance cream used externally containing hamamelis virginiana distillate and zinc oxide which is marketed in 30 g, 60 g and 90 g aluminum tubes
- The Hamamelis virginiana aqueous extract present in HAMAZINC composition has tissue constrictor (astringent), local stops bleeding (hemostatic) and reduces inflammation (anti-inflammatory) activities
- Following skin injuries, the tissue constrictor effect provides tissue thickening by causing coagulation of skin 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 reduces inflammation and tissue death in damaged and injured skin and accelerates wound healing in the injury site by increasing skin cell growth.
- **HAMAZINC;**
    - 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/sunburn
    - Superficial skin lesions (injuries) including scratches and cuts
    - Care and prevention of cracked nipples in nursing mothers
    - Care and protection of dry, cracked, split skin (including skin of the elderly and treatment of diabetic foot)
    - This product can be used as an adjunct to treatment of skin disease which is manifested with tissue disorders such as redness, itching, exudate, scabbing caused by various reasons as a result of treatment with other medicines, rapidly growing and exuding wound like skin damage due to rubbing or microbes such as fungus on skin and especially leg wounds and wounds that occurs in patients lying down for a long time

## **2. Before you use HAMAZINC**

### **DO NOT use HAMAZINC**

Do not use if you are allergic to any of the ingredients of HAMAZINC.

### **TAKE SPECIAL CARE with HAMAZINC in the following conditions**

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

If current complaints persist or worsen despite using HAMAZINC, a doctor should be consulted.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

### **Using HAMAZINC with food and drink**

There is no special indication regarding using HAMAZINC with food and drink.

### **Pregnancy**

*Ask your doctor or pharmacist for advice before taking the medicine.*

For Hamamelis virginiana, no clinical data on exposed pregnancies are available.

For zinc oxide, no clinical data on exposed pregnancies are available.

Animal studies are also unavailable.

Caution should be used if HAMAZINC is to be used during pregnancy.

*If you notice that you are pregnant during treatment, please consult your doctor immediately.*

### **Breast-feeding**

*Ask your doctor or pharmacist for advice before taking the medicine.*

It is not known whether Hamamelis virginiana passes into human milk.

Excretion of Hamamelis virginiana into milk in animals was also not investigated.

It is not known whether zinc oxide passes into human milk.

Consult your doctor about using HAMAZINC during lactation.

### **Driving and using machines**

There is no known effect on driving and using machines.

### **Important information about some of the excipients of HAMAZINC**

Local skin reactions (for example, contact dermatitis with irritant or allergic ingredients directly associated with skin inflammation) and skin irritation may rarely occur due to propylene glycol and cetostearyl alcohol contents.

The methylparaben (E218), ethylparaben (E214) and propylparaben (E216) contents of HAMAZINC may cause allergic (potentially delayed) reactions.

### **Using with other medicines**

No interaction of HAMAZINC with other medicinal products via the topical route was reported.

*Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.*

### **3. How to use HAMAZINC?**

- **Instructions for appropriate method and dose/frequency of administration:**

Apply HAMAZINC few times a day to the lesion area.

There is no time limitation to using HAMAZINC.

- **Route and method of administration:**

Apply HAMAZINC 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.

- **Various age groups:**

#### **Use in children:**

Not reported.

#### **Use in elderly:**

Not reported.

- **Special Populations**

#### **Kidney/Liver failure:**

Not reported.

*If you have the impression that the effect of HAMAZINC is too strong or too weak, talk to your doctor or pharmacist.*

**If you have used more HAMAZINC than you should:**

*If you may have taken more HAMAZINC than you should, talk to a doctor or pharmacist.*

**If you forget to use HAMAZINC:**

*Do not use double dose to make up for the dose you forgot.*

**If you stop using HAMAZINC:**

No effect is expected.

**4. Possible side effects**

Like all medicines, side effects can occur in people sensitive to the contents of HAMAZINC.

**If any of the following occur stop using HAMAZINC and IMMEDIATELY inform your doctor or go to the nearest emergency department:**

- Swelling of hands, feet, ankles, face, lips or specific swelling of mouth cavity and throat causing difficulty in breathing

These are very serious side effects. If you have any of them, this means you have serious allergy for HAMAZINC. You may need emergency medical care or hospitalization.

All of these very serious side effects occur very rarely.

Side effects are classified by the following categories:

Very common (occurring in at least 1 of 10 patients);

Common (occurring in less than 1 of 10 but in more than 1 of 100 patients);

Uncommon (occurring in less than 1 of 100 but more than 1 in 1.000 patients);

Rare (occurring in less than 1 in 10.000 patients);

Very rare (occurring in less than 1 of 10.000 patients);

Unknown (Cannot be estimated from the available data),

**Uncommon** (occurring in less than 1 of 100 but more than 1 in 1.000 patients)

- Skin rashes that spread uniformly in the skin, suddenly spontaneously, and disappear without recurring skin changes, symptomatic skin rash (exanthema)
- Skin irritation, itching, burning and stinging sensation
- Skin redness (erythema)
- Dry skin

**Unknown** (cannot be estimated with the available data)

- Allergic reaction
- Skin irritation (eczema), which is caused by irritant or allergenic substances, direct skin contact inflammation (contact dermatitis), tissue disorders such as redness, itching, watering, incrustation
- Hives (urticarial), allergic skin rash
- Allergic skin disorder (angioneurotic edema) caused by large, painless swelling that is restricted to a certain area under the skin

*If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.*

**5. How to store HAMAZINC**

*Keep in the original package and out of the reach and sight of children.*

Store at room temperature below 25 °C

**Use in accordance with the expiry date.**

*Use HAMAZINC before the expiry date indicated on the tube or package.*

Do not use HAMAZINC if you notice any damage to the product and/or package.

***Marketing authorization holder:***

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

[info@berko.com.tr](mailto:info@berko.com.tr)

***Manufacturer:***

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

*This patient information leaflet was last approved on 28/05/2018.*