SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aflofarm boric ointment, 10 g/100 g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

100 g of the ointment contain 10 g of boric acid *(Acidum boricum).*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dermatitis, burns, slight epidermal damage.

4.2 Posology and method of administration

Topical use on the skin.

Adults and children above the age of 12: apply to the pathologically altered sites usually once or twice daily.

4.3 Contraindications

- Hypersensitivity to the active substance or to any other excipient listed in point 6.1;
- Extensive wounds or damaged mucous membranes;
- Open wounds and cuts;
- Children younger than 12.

4.4 Special warnings and precautions for use

Use with caution on weeping wounds or extensive inflammatory changes.

4.5 Interaction with other medicinal products and other forms of interaction

Agents that cause local hyperaemia of the skin may increase the risk of product absorption.

4.6 Effects on fertility, pregnancy and lactation

This medicinal product can be used in pregnant and breastfeeding women when the benefit to the mother outweighs the risk to the fetus or child.

4.7 Effects on the ability to drive and use machines

The medicine does not affect the ability to drive or use machines.

4.8 Undesirable effects

Possible undesirable effects are listed below according to the System Organ Class.

Skin and subcutaneous tissue disorders
Unknown frequency: regional skin irritation

Gastrointestinal disorders
Rare: diarrhoea, bloody stools, vomiting

Long-term use of the medicine on large areas of damaged skin may cause the accumulation of boric acid in the organism and lead to chronic poisoning.

4.9 Overdose

As of today, no instances of an overdose have been reported. In the case of an overdose, symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antiseptics and disinfectants.

ATC code: D08AD

Boric acid has a mild bacteriostatic and fungistatic effect. Due to acidification, the ointment has astringent properties, dries the skin and has a mild antiseptic effect.

5.2 Pharmacokinetic properties

Distribution

Following absorption of the product that contains boric acid from the gastrointestinal tract, mucous membranes or damaged skin, approximately 50% of the dose is excreted within 24 hours. Boric acid absorption through undamaged skin is practically unobserved.

Metabolism

Boric acid demonstrates affinity to the cis-hydroxyl group, both *in vivo* and *in vitro*. This may explain its biological effects. This reaction is reversible.

Elimination

Boric acid is eliminated mainly by the kidneys (<90%) in an unaltered form. Slight amounts of boric acid are eliminated in the sweat, saliva and faeces.

5.3. Preclinical safety data

No sufficient non-clinical data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White petrolatum jelly

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

Life after the first opening of the tube – 28 days.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.

6.5 Nature and contents of container

Aluminium tube with a protective membrane and a polyethylene cap in an outer carton;
1 tube – 20 g

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Aflofarm Farmacja Polska Sp.
z o.o. ul. Partyzancka 133/151
95-200 Pabianice, Poland

8. MARKETING AUTHORISATION NUMBER

Authorisation No EL-5141/ChF

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of the first authorisation: 15 December 2000

Date of the latest renewal of the authorisation: 10 December 2008

10. DATE OF (PARTIAL) REVISION OF THE TEXT OF THE SUMMARY OF PRODUCT CHARACTERISTICS