PACKAGE LEAFLET: INFORMATION FOR THE USER

Brucelin® 5% w/w gel,
Amikacin sulfate

1. IDENTIFICATION OF THE MEDICINAL PRODUCT

1.1. Trade name

Brucelin®

1.2. Composition

Active substance: Amikacin sulfate.
Excipients: Hydroxyethylcellulose, Glycerine, Methyl-p-hydroxybenzoate, Propyl-p-hydroxybenzoate, Water purified.

1.3. Pharmaceutical form

Gel.

1.4. Quantitative composition

Each g or gel contains 66,75 mg amikacin sulfate, equivalent to 50 mg amikacin.

1.5. Description – Packaging

Carton box containing a 30g tube and a package leaflet..

1.6. Pharmacotherapeutic group

Antibiotic.

1.7. Marketing Authorization Holder

TARGET PHARMA LTD.
54 Menandrou str., 104 31 Athens - Greece
Tel.: +30 210 5224830, Fax: +30 210 5224838,
E-mail: info@targetpharma.gr, http://www.targetpharma.gr

1.8. Manufacturer

PHARMACEUTICAL INDUSTRY PROEL EPAM. G. KORONIS S.A.
9 Dilou str., 12134 Peristeri, Attica – Greece
Tel.: +30 210 5755711, Fax: +30 210 5748398

2. WHAT SHOULD THE PATIENT KNOW ABOUT THIS MEDICINE

All information in this leaflet refers to the medicinal product Brucelin®, that your doctor prescribed for you. Please read carefully. You will receive important information, but not everything can be explained in this document. If you have more questions or if you are not sure about something in this leaflet, ask your doctor or pharmacist.

2.1. General information

The below mentioned pharmacodynamics specifications are referring to the general use of amikacin.
Amikacin is an aminoglycoside, semisynthetic antibiotic. It acts through a similar mechanism of action as other aminoglycoside antibiotics, i.e. by inhibition of protein synthesis in bacteria. In vitro, amikacin is active against a wide range of bacteria, inhibiting not only gram positive but also gram negative bacteria such as: *Staphylococcus aureus* (including strains resistant to penicillin and methycilline), *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, positive and negative *Proteus indole*, *Providentia stuartii*, *Salmonella* spp, *Shigella* spp, *Acinetobacter*. Amikacin is resistant to the majority of the catabolic enzymes that deactivate other aminoglycosides. Finally, bacterial strains that show resistance to gentamycin, tobramycin and canamycin, are proven to be sensitive to amikacin.

2.2. Indication

Brucelin® is indicated in:
- Skin infected trauma, skin and mucosa erosions, pyodermias and other similar conditions due to Pseudomonas or other bacteria that are sensitive to amikacin.

Also topically the product can be used in:
- Stasis ulcers or ischemic ulcers (due to artery disease, hypertension or diabetes), where the product should be administered with caution in cases where lab results indicate that the ulcer is infected by sensitive in amikacin bacteria.

2.3. Contraindications

All medicines may help the patients but they can also cause issues when the administration in not according to the doctor's instructions.
Brucelin® should not be used by patients that are allergic (hypersensitive) to amikacin or other aminoglycoside antibiotics or in any other of the excipients of the product.

2.4. Special warnings and precautions for use

During systemic administration of amikacin (per os or through injection) has been reported the possibility to cause renal toxicity, neuro/ototoxicity, neuromuscular toxicity.
This is not expected during the topical administration of **Brucelin®** gel.
In this case you should know the following:
- It may be observed cross-allergy reaction when other aminoglycoside antibiotics are concomitantly administered.
- As with other antibiotics, topical administration of amikacin may cause super infection due to resistant microbial. In such cases, amikacin should be stopped and the patient should receive the proper therapy.
- **Brucelin®** should not be used during pregnancy. If the use of amikacin is essential for the patient, it should be administered under strict supervision by the prescribing physician.
- **Brucelin®** should be avoided in breast-feeding mothers and infants. In cases where the use of amikacin is essential for the mother, breast-feeding should be stopped.

2.5. Interactions with other medicines or substances

Before you administer this product, you should inform your doctor about any other medication that you are taking, including those that you buy without prescription.
During the systemic use of amikacin interactions have been reported during co-administration with diouretics, other aminoglycosides, cefalosporines, colistin or paromomycin.
During the topical administration of amikacin no such interactions have been reported.

2.6. Dosage

Follow your doctor's instructions regarding when and how you should administer this product. Before using the product for the first time, READ CAREFULLY the instructions for use. Ask your doctor or pharmacist if you are not sure how to use the product.

Route of administration: It is always administered externally, topically.
It is recommended that the affected skin area should be carefully cleaned first and then an amount of **Brucelin®** should be gently administered.
Dosage:
Adults and elderly: **Brucelin®** should be smeared in the affected area and in a surface of 3-5 cm (depending on the area size of the infected skin) once daily.
Children: Unless otherwise recommended, the dosage in children is the same as indicated for adults. **Brucelin®** should not be administered in children that are younger than 30 months old.

2.7. Overdosage – Treatment

Due to the pharmaceutical form and the route of administration, it is not expected to cause any clinical problems
IN CASES OF OVERDOSAGE, YOU SHOULD ALWAYS ASK YOR DOCTOR'S OR PHARMACIST'S ADVISE OR YOU SHOULD CASS TO THE POISON CENTER OF ATHENS TEL.: +30 210 7793777.

2.8. What should the patient know if fails to take a dose

If you miss a dose and you realize it quickly, then you can take the missed dose and continue as scheduled for the next dose.
If the time for the next dose is approaching, then you can skip the missed dose and take the next as scheduled.

2.9. Possible side effects

Like all medicines, Brucelin® may cause not only benefits but it may cause and side effects. Such side effects do not occur to all patients and not very often. In case you experience any side effect you should inform you doctor or pharmacist in order to receive the necessary instructions.

The possible side effects that may occur during the systemic use of amikacin are linked to the systemic administration of high dosages or with long-term treatment. These are: Ototoxicity, renal toxicity, skin rashes, neuromuscular blockade etc. that appear showing:

- In ototoxicity (mainly of the main acoustic nerve) reduced hearing ability, initially for sounds of high frequency, tinnitus or vertigo.
- In renal toxicity, presence in urine of albumen, cylinder, red and white blood cells, hyperazotaimia, oliguria and renal deficiency.

It may also occur: fever, eosinophilia, nausea, vomiting, headache, tremor, paraesthisia (hallucinations), anemia, hypotension and elevation of transaminase levels.
Such side effects have been very rarely reported in the topical external administration of amikacin.
For the administration of **Brucelin®** it should be considered that rarely hypersensitivity and local rash have been reported.
The above mentioned side effects should not alert the patient. Most probably the patient will not experience any of them during external topical administration of the product.

If you think that the product caused to you any side effects, please inform your doctor or pharmacist or other health care professional or directly to the National Medicines Agency (284 Mesogion Av., 15562, Cholargos, www.eof.gr).

2.10. What should the patient know about the expiration date

The expiration date appears in the carton of the product and on the tube (EXP).
No medicine should be used after the expiration date.

2.11. Special warnings about the storage of the product

Store **Brucelin®** in the initial container in temperature below 25˚C.

2.12. Date of last revision of this text

January 2014

3. INFORMATION FOR THE RATIONAL USE OF MEDICINES

- This pharmaceutical product was prescribed by your doctor to you, according to your medical history and condition. Do not pass the product to others or use it in any other condition even if the symptoms may appear the same and without receiving your doctor's or pharmacist's advice.
- If during treatment with this medicine you experience any problem or issue, contact immediately your doctor or pharmacist.
- If you have any questions regarding the information for this product, its use or about the medical condition that you suffer, you should ask your doctor or pharmacist.
- This product will be safe and effective if it is used exactly according to instructions provided.
- For your own safety it is highly recommended that you read carefully all information provided for the prescribed medicine.
- Do not store medicines in bathroom lockers, as the high temperature and the humidity may degrade the product which may be harmful to your health.
- Store the product in the original packaging.
- If your doctor instructed you to stop the use of this product, dispose the remaining product and do not use it.
- Do not keep the medicine you do not need any more or those that are expired.
- Keep all medicines in safe place out of reach and sight of children.

4. PRESCRIBING INFORMATION

Brucelin® is administered only by medicinal prescription.