

NIKA®-Cast / NIKA®-Zink Zinc Paste Bandages

Instructions for use

DISCLAIMER

This product may only be used in combination with the corresponding original products or with third-party products approved by the manufacturer for this application according to the instructions and recommendations of NIKA® Medical Produkte GmbH. If third-party products which are not approved for this application by NIKA® Medical Produkte GmbH will be used in combination with products of NIKA® Medical Produkte GmbH the warranty will expire and any other express or implied obligations of NIKA® Medical Produkte GmbH will become null and void. The user of NIKA® Medical Produkte GmbH products has to determine whether the product is suitable for a specific patient under the present circumstances. NIKA® Medical Produkte GmbH will not be responsible, either express or implied, for direct or indirect damages, penalty including compensation or any other damages which may occur by or in combination with errors associated with professional judgment or application within the framework of the use of NIKA® Medical Produkte GmbH products. Furthermore, the user is obliged to inform himself regularly about the latest developments regarding this product of NIKA® Medical Produkte GmbH product and its application. In case of doubt NIKA® Medical Produkte GmbH has to be contacted. Since the use of the product rests on the user's control he himself will be responsible. NIKA® Medical Produkte GmbH will assume no liability for damages resulting from the use of the product. We would like to point out that some products listed in this user's instruction may not be licensed or approved for sale in all markets.

APPLICATION RANGE OF THE USER'S INSTRUCTION

This user's instruction is valid for the products described.

Table 1: Application Range of the User's Instruction

| REF | Pharmacy No. | Product Size |
|--|--------------|--------------|
| NIKA®-Cast elastic Zinc Paste Bandage | | |
| 620406 | 13913914 | 4m x 6cm |
| 620805 | - | 5m x 8cm |
| 621005 | 02465996 | 5m x 10cm |
| 620607 | - | 7m x 6cm |
| 620807 | 02646539 | 7m x 8cm |
| 621007 | 02466004 | 7m x 10cm |
| 621010 | 02466010 | 10m x 10cm |
| NIKA®-Zink non-elastic Zinc Paste Bandage | | |
| 601005 | 02465861 | 5m x 10cm |
| 601007 | 02465890 | 7m x 10cm |
| 601010 | 02465909 | 10m x 10cm |

PRODUCT INFORMATION

General Product Information

The present product is a viscose compress impregnated with zinc paste which is provided in airtight packaging and will harden in the ambient air when it is used.

INTENDED USE, INDICATIONS AND CONTRA-INDICATIONS

Intended Use

The non-sterile zinc bandage compress is purposed for wrapping body parts with intact skin if indicated correspondingly.

Indications

Zinc paste bandages may be used in the presence of the following indications:

- Muscle soreness
- Muscle strains
- Torn muscle fibres
- Contusions
- Sprains
- Post-traumatic swellings
- Sports trauma involving tendons, muscles or joints.

Contra-indications

Zinc paste bandages may not be used in case of the following contra-indications:

- existing hypersensitivity or allergy to zinc oxide
- existing hypersensitivity or allergy to any other product ingredient
- no application on open wounds



If during the treatment other components are used which are not covered by the scope of these instructions for use, the corresponding instructions for use have to be checked carefully in advance.

GENERAL INFORMATION

100% guarantee of treatment success cannot be granted when using the products described in these instructions for use. Ignoring potentially specified restrictions of use and procedures may lead to malfunction.

Close cooperation between all involved persons from the medical sector and the patient himself is essential for successful treatment.

Improper handling may lead to damage of the product or to complications. Therefore, the products have to be used only by appropriately trained staff with corresponding knowledge and skills.

APPLICATION

Preparation

1. Before applying the zinc paste bandage the limb has to be elevated until it shrinks and the corresponding body region must be thoroughly cleaned and greased.
2. Then the skin has to be covered with a padding bandage (NIKA®-Flex or NIKA®-foam bandage) before the zinc paste bandage will be applied.
3. Pressure-sensitive areas (ridge of the tibia, ankle, back of the foot) can be padded additionally.

Bandaging

1. The zinc paste bandage must be applied under even tension in steep spiral turns, starting at the basal joints upwards to the joint.
2. Free areas of the limb in question must be covered with further spiral turns.
3. Knee or elbow joint should not be bandaged for the sake of flexibility.



Make sure that the bandage will be unrolled directly at the limb with pressure from the entire bandage width to avoid constriction and pressure edges.

4. To protect the clothing an elastic gauze bandage (NIKA® gauze or a stockinette e.g. NIKA®-Fast or NIKA®-Tricot) can be pulled over the zinc paste bandage.
5. To obtain compression a NIKA® ideal bandage or a NIKA®-Grip compression tubular bandage may be used.
6. Immediately after the zinc paste bandage has been applied the patient can move around.

Follow-up

The attending physician is responsible for the change of the bandage and the follow-up. Usually the first bandage will be renewed after 2 to 6 days.

HANDLING AND STORAGE INFORMATION

The product must be always protected from sunlight and must be stored in a dry place. Storage at room temperature is recommended.



After the expiry date the product must no longer be used and must be disposed of properly.

NOTIFICATION OBLIGATION

All serious incidents which occurred by using the product (defined as „incidents which have led, could have led or could lead directly or indirectly to death or serious deterioration in the condition of a patient, a user or any other person) have to be reported immediately by the user to the manufacturer and to the Federal Institute for Drugs and Medical Devices at <https://www2.bfarm.de/medprod/mpsv/>.

FURTHER INFORMATION

Information on Components

Basic bandage: viscose und polyamide

Zinc paste: water, glycerine, zinc-oxide, carboxy-methylcellulose, gelatin and preservatives

Disposal

Disposal of the product has to be carried out in accordance with the local and environmental regulations taking into account the individual contamination level.



Manufacturer



Country and date of manufacture



Instructions for use



Do not reuse



Attention



Expiry date



Medical Device



Reference Number



Lot Number



Unique Device Identifier



Keep away from sunlight



Keep in a dry place



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