

## WARNINGS and CONTRA-INDICATIONS

DO NOT USE THE PRODUCT UNDER ANY OF THE FOLLOWING CONDITIONS:

- Conditions pertaining to the product
  - If the "use-by" date of the product (printed on the outer packaging) is reached.
  - Do not buy or use damaged or leaked products.
  - Do not buy or use products whose labels are incomplete or unreadable. If you happen to buy them consult the Manufacturer.
  - Do not use before consulting a physician.
  - Do not use used products.
- Conditions pertaining to the patient
  - If the Patient is pregnant or suspect pregnancy.
  - If the Patient has an anaphylactic reaction history.
  - If the Patient is diagnosed with diabetes mellitus.
  - If the Patient is diagnosed with a tumour in the vicinity of herniated disk area.
  - If the Patient is diagnosed with severe paravertebral muscle spasm.
  - If the Patient is diagnosed with strength loss 3/5 or more in any muscle group or neurological deficit.
  - If the Patient is diagnosed with asthma (the product may trigger an attack due to its strong odour).

## Instructions for Use

### ARTCURE® Diffusional Patch (DP)

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- If the Patient will travel long-distance (for longer than 2 hours) or by airway within 1 week following application.
- If the Patient will not be able to stay in bed lying back for 24 hours following the application (except for inevitable needs such as very short eating and toilet breaks). Otherwise, the product will become useless and will not perform.
- If the Patient needs to take shower or bath or alike during 24 hours following application. Otherwise, the product will become useless and will not perform.
- If the skin in the application area is not intact (it must be free of cuts and wounds in order to prevent infection occurrence).

### CAUTIONS

- In case of giant disk herniation, use of the product may pose a risk of neurological deterioration. Before using the product, the Patient must consult a physician to be prepared for such a situation.
- If the Patient has atopic skin, the product may cause excess irritation for a duration of 24 to 72 hours. Before using the product, the Patient must consult a physician to be prepared for such a situation.
- The product performs best when disk hernia is **NOT** accompanied by one or more of foraminal stenosis, lumbar spinal stenosis, Black Disk or disk calcification. In such a case, product performance may decrease considerably. Yet, usage will not result in worsening of the Patient's status or any adverse reaction.
- Product performance may be low at early stages of disk hernia (called as disk degeneration or bulging).
- This product doesn't have to be applied in a healthcare facility or by a health professional provided that a physician is consulted beforehand for guidance.
- This product is used alone and by no way can be used in combination with another product.
- Do not process (washing, heating, etc.) the product in any way prior to use.
- Do not attempt to sterilise the product. This is not necessary.
- No supporting device (electrical, mechanical, medical, etc.) or heater or whatsoever is needed for application of this product. Everything needed for application is already included in the package.
- Rarely, pain perceived by the Patient may relatively increase (as compared to the pain prior to application) especially during the period 4 to 12 hours (it might occasionally extend up to 24 hours) following application. This should be considered normal. The pain will vanish by itself after 12th hour (occasionally after 24th hour). But, if the Patient's level of pain reaches an unbearable level, painkillers and/or myorelaxants can be used.
- The Patient applied the product can continue drugs for chronic diseases. No drug restriction is necessary.
- This product is for single use. If it is re-used, this attempt will be useless and bring no benefit. No adverse effect, except for hygiene, is to be expected. However, if the part of skin on which the product was re-used was not intact, this situation could pose infection risks.
- Application can be REPEATED with a new product, when deemed necessary by a physician.
- Following the application, the Patient must be attentive to recurrence in daily life. This disease is quite prone to recur.
- The performance of the device is not expected to change if it is stored or transported according to the conditions given on stickers. Do not use the product if there is, a leakage in the primary package or a tear in the cotton upper layer of the product. Do not use the product if there is an impairment suspect and contact the Manufacturer.
- The product is cytotoxic. Please remove the product from the herniated region of your body after 24<sup>th</sup> hour.