



ARTCURE® PW Diffusional Patch (DP)

ENGLISH

THIS PRODUCT MUST BE USED
UNDER DOCTOR CONTROL AND
CONSULTANCY

Dear Patient;

- Before you start using this medical device, please carefully read this user manual which contains important information for you. The information provided here is not only providing safe use, but also the details needed to get the most benefit from the product.
- Please keep this user manual. You may need it later.
- If you do not understand or not sure that you understand any of the information given in this user manual, consult your doctor.
- Consult your doctor if you experience any side effects, whether or not indicated in this user guide.
- This product does not have to be applied by a healthcare professional or healthcare professional, in consultation with a doctor prior to use.





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1. PACKAGE CONTENT

1. Outer packaging
2. This manual
3. Tube containing gel to be applied to two patches
4. Inner packing (aluminum wrapped with heat treatment) and in this package:
 - Patch (ARTCURE® PW Diffusional Patch)
 - 5 hypoallergenic adhesive tapes
 - Gel dispensing apparatus
 - 2 cannulas

2. DISC HERNIA DISEASE

There is a structure called the intervertebral disc which acts as a pillow between the vertebrae forming the vertebrae. The inside of this structure is in the form of gel and the nucleus is called pulposus and it contains 80-90% water. The nucleus pulposus is surrounded by a very elastic and rigid structure called annulus fibrosus. If the annulus fibrosus is torn or damaged, the gel-like part flows outwards through the spinal canal. This medical condition is called spinal disc herniation (hernia disc). If the Hernia disc presses on the spinal nerve, the resulting clinical picture is

called disc herniation.

3. ABOUT ARTCURE® PW DIFFUSIONAL PATCH

3.1 PRODUCT DESCRIPTION I

The ARTCURE® PW Diffusional Patch is a medical device intended to alleviate and treat disc herniation in humans. The ARTCURE® PW Diffusional Patch affects the hernie disc structure due to the diffusion mechanical effect of changing the osmotic process in the hernie disc.

3.2 PRODUCT FEATURES

- ARTCURE® PW Diffusional Patch can be applied at medium to advanced levels in herniated disc protruded, extruded, fragmented and sequestered disc herniation.
- The risk of recurrence is extremely low because ARTCURE® PW Diffusional Patch maintains anatomical integrity throughout the application. (Except in cases where inappropriate or excessive physical activity of the patients following the application is caused,

- ARTCURE® Diffusional Patch reduces the interruption of patients' daily lives at significant rates. Healing is felt within 24 hours. Almost all of the performance that can be obtained from the end of 48 hours is reached.
- ARTCURE® PW Diffusional Patch is presented in sterile condition.
- ARTCURE® PW Diffusional Patch can be applied at medium to advanced levels of disc hernia.
- From ARTCURE® PW Diffusional Patch box, the dose obtained by squeezing all 2 tubes coming out of the box into the patch is used.
- As far as warning and safety information is concerned, the risks to implementation are very low.

- For more information:

www.artcure.com

3.3 PRODUCT MODELS/TYPES

Artcure® Diffusional Patch is a ready for use patch. Artcure® PW Diffusional Patch is a patch prepared by combining parts before use. The patch sizes are the same for both types.

3.4 PRODUCT FEATURES

FEATURES	VALUES
Patch Size	Length: 22-24 cm, Width: 12-14cm, Depth: 0,2cm
Shipment Weight	210 +/-10 gr
Smell	Characteristic and sharp
Gel Viscosity	13,000-50,000 milipascal seconds
Gel Brix	%70-%75
Shipping / Storage Temperature	Keep at room temperature
Medical Device Class	Class IIb, Medical Device Regulation

3.5 REASONS OF USE UNDER DOCTOR CONTROL

- Ensure that causes of waist and neck pain are excluded from the causes of disc herniation
- Acquisition of MRI Results of the patient: These images are required for precise detection and marking of the point where the hernia disc is present before ARTCURE® PW Diffusional Patch application.
- Follow-up of treatment: MR images taken before and after the application of ARTCURE® PW Diffusional Patch are needed to make comparisons and thus confirm that the radiological correction has been applied. MR imaging also shows the level of disc herniation.
- Compliance of the Product to the Patient: The patient should not use the product in some cases. (See section on Alerts and Contraindications); these conditions, if any, should be controlled and determined by a doctor.
- Expected Product Performance: ARTCURE® PW Diffusional Patch gives the best result in cases where one or more of the foraminal stenosis, lumbar narrow channel, black disc ,

calcified disc herniation diseases do not accompany disc hernia disease. The product may still provide correction, but the doctor's diagnosis is necessary to keep the expectations at a realistic level.

- Side Effects Control and Preparedness: Depending on the individual conditions of the patient, it may cause side effects (see Side Effects section). Consult a doctor before using the product to determine the suitability of indication and other diseases accompanying the symptoms.



4. WARNINGS AND CONTRADICTIONS

NEVER USE THE PRODUCT IN FOLLOWING CASES;

Product-related situations

- Do not use if the product's "expiry date" is passed (written on the outer packaging).
- Do not buy or use damaged or leaking products.
- Do not buy or use products whose labels are missing or unread. If you have purchased it, contact the manufacturer.
- Before you use the product, consult your doctor.
- Do not reuse used products.

Product-related situations

- If the patient is pregnant or has a pregnancy doubt,
- If the patient has an anaphylactic reaction history,
- If the patient is diagnosed with diabetes,

- If tumor is located adjacent to the disc herniation zone of the patient
- If the patient has a loss of power or neurological loss of 3/5 or more in any muscle group,
- If the patient is diagnosed with asthma (product smell may trigger an asthma attack)
- If the patient is going to travel for a long period of time (2 hours or more) within 1 week after the application or he/she is going to make an airplane trip,
- Otherwise, the product will become unusable and will not be able to perform its functions unless the patient is able to rest in the supine position for the first 24 hours after application (except for short-time meals or toiletries).
- If there is damage in the application area (there should be no cuts or wounds in the application to prevent the risk of infection)

5. MEASURES

- There is a risk of transient neurological deterioration in giant disc herniation cases after use of this product. To be prepared for such a situation, the doctor should be consulted before use.
- If the patient has an atopic skin structure, excessive skin irritation may occur for a period of 24 to 72 hours after application. To be prepared for such a situation, the doctor should be consulted before using the product.
- The product performs better in situations where one or more of the foraminal narrow channel, spinal narrow channel, black disc or disc calcification diseases DO NOT accompany the disc herniation disorder. In such a case, product performance may reduce significantly. However, it does not cause worsening or any negative reaction in the case of the patient.
- Product performance may be low in the early stages of disc herniation (disc degeneration or bulging).
- There is no obligation for this product to be implemented by a health care provider or health care professional as long as consultation with a doctor



is available for guidance before implementation.

- This product is used alone and cannot be combined with any other product.
- Processing (washing, heating, etc.) is strictly prohibited before application.
- Do not try to sterilize the product. This is not necessary.
- There is no need for any supporting device (electrical, mechanical, medical, etc.) or any heater-like device to apply the product. Everything needed for the application is available in the package.
- Rarely, from 4th to 12th hour after application (in some cases up to 24 hours), there may be an increase in the amount of pain felt prior to application. This is normal. The pain will end after the 12th hour (in some cases after 24 hours). If the patient's level of pain reaches a very disturbing level, a painkiller and/or muscle relaxant may be used under control of doctor.
- The patient whom the product is applied may continue to take medicines that he/she uses for his/her chronic illnesses. There is no restriction on the use of medicines.
- The product is disposable. In the case of reuse, this application will be

useless and will provide no benefit. In case of reuse, no adverse effects other than hygiene are expected. If the area of the reapplied region is damaged, a risk of infection may occur.

- If required by your doctor, the 2nd dose may be administered. The minimum time between the first application and the 2nd application should be 15 days. This product can be applied no more than 2 times a year.
- The patient has to be careful about the recurrence of disc herniation in daily life after the application. This disease has a high tendency to recur.
- Although it is not foreseeable whether the performance of the appliance will change under proper storage and transportation conditions, do not use the product if there is leakage from the packaging of the primer or there is rupture on the upper surface of the product after the product is opened. If in doubt, do not use the product and contact the manufacturer.
- The product is cytotoxic. Do not hold it on your body for more than 24 hours.

6. SIDE EFFECTS

There are only a few side effects of ARTCURE® PW Diffusional Patch. Patients with atopic or sensitive skin may experience crusting, erythema, redness, inflammation, irritation and excessive irritation on the application area. However, this situation is temporary and does not require any treatment. If patient prefer, skin nourishing and/ or restorative creams may be used for relaxation and aesthetic purposes following application. From the practical experience, the frequency of side effects has been determined as follows.

Very common side effects(visible in at least 1 of 10 patients) Mild itching and very mild redness on the application area

Common side effects(less than 1 in 10 patients but more than 1 in 100 patients) Mild skin irritation (irritation and erythema)

Uncommon side effects(less than 1 in 100 patients but more than 1 in 1000 patients). Severe skin irritation (excessive irritation, impaired skin integrity, erythema scaling)

Furthermore, the risk of anaphylaxis which is assessed in the "Serious Negative Event" class may be a concern



for all users. Especially the patients who are sensitive to one of the ingredients and who have anaphylaxis in the past are not recommended to use the product.

7. STORAGE CONDITIONS

- Do not open the inner packaging until the moment of use.
- Do not heat or freeze.
- Protect from direct sunlight.
- Keep out of reach of children.
- Keep at room temperature (25 oC)

8. DISPOSAL

There are no precautions to take for any special or unusual risk related to the disposal of the product. The product may be disposed of as household waste after the application and removal from the patient.

No part of the patch or packaging used should be flushed. Recyclable elements must be disposed of properly.

9. PRODUCER

Commercial Title:

Metuas Medikal, Sağlık Hizmetleri, Danışmanlık, İthalat, İhracat A.Ş. (In short, METUAS) Address: İlkbahar Mah. Konrad Adenauer Cad. Yalçın Apt. 75 / 10 Çankaya / Ankara - Türkiye

10. SCOPE OF LIMITED WARRANTIES AND LIABILITIES

- a. METUAS warrants that the ARTCURE® PW Diffusional Patch will not have workmanship and/or material imperfections from the date of manufacture to the end of its shelf life or to the moment of consumption, whichever occurs first.
- b. If METUAS receives a damage notification under any METUAS warranty in any jurisdiction within the valid warranty period, it will repair or replace the defective product at its option. All return issues must be notified in advance to METUAS. If METUAS cannot repair or replace the defective product under warranty, it will refund the purchase price of the product within a reasonable time following the error notification.

- c. METUAS has no obligation to repair, replace or refund the product until the customer has sent the defective but unused product to METUAS. All returned products will be PROPERTY of METUAS.
- d. The changed product will be new one or new-like, provided that it at least meets the functionality of the previous product.
- e. The limited warranty provided by METUAS is valid in the countries in which the product is marketed by METUAS or METUAS' authorized representative for the related country.

Guarantee Limit

METUAS or its third party suppliers will not be liable for any warranties, express or implied, and cannot make any commitment to merchantability, satisfactory quality or fitness for a particular purpose.

Limitations of Liability

- a. To the extent permitted by local law, the rights granted in this limited warranty statement are the sole and exclusive rights of the customer.
- b. METUAS or its third party suppliers



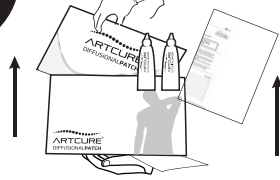
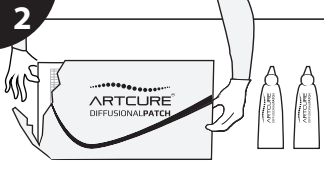
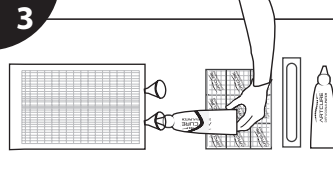
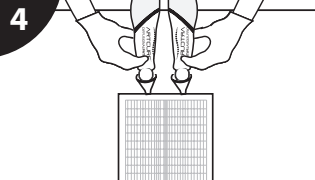
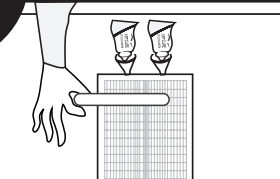
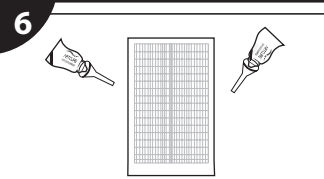
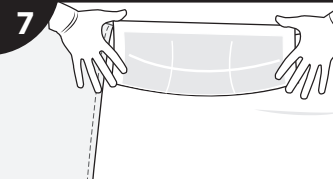


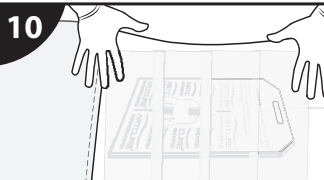


cannot be held liable for any indirect, incidental or consequential damages in respect of medical expenses incurred in connection with the performance or use of the product, whether in contract, tort, unfair treatment, warranty or any other relief.

11. USED SYMBOLS AND MEANINGS

The meanings of the information symbols on ARTCURE® PW Diffusional Patch packaging are given below.

SYMBOL	MEANING
	See user guide
	Attention, see the documentation of this product
	Do not use if the packaging is damaged or opened.
	Do not reuse
	Store in dry environment
	Keep away from sunlight
	Keep at room temperature
	Expiration date
	Production date
	Product LOT number
	Subjected to sterilization
	Can not be re-sterilized

12 APPLICATION GUIDE The application is illustrated below. After the application, THE PATIENT SHOULD REST ON BED IN SUPINE POSITION FOR 24 HOURS.

			
<p>Open the cardboard box. Take the primer package, booklet and 2 gels out of the box. The outer package may be different than shown in the Picture.</p>	<p>Tear off the side of the primer package and remove the patch, sterile gel emitter and 5 tapes.</p>	<p>Screw both gels to the applicators on the patch.</p>	<p>Discharge all of the gel into the patch.</p>
			
<p>Using the sterile spreader, spread the gel to the whole of the patch.</p>	<p>Remove the applicators on the patch together.</p>	<p>Locate the patch in such manner that it completely covers the hernia disc and the porous side contacts with the skin.</p>	<p>Make sure that the patch is in line with the spinal cord and hernia zone.</p>
			
<p>Adhere the papers on the hypoallergenic tape taken out of the box in such manner to fix the patch.</p>	<p>Adhere the other tapes in such manner that they cover each other partially and cover the patch.</p>	<p>In the application of the neck, locate the patch in such manner that it contacts with skin from 1 finger lower than the neck end.</p>	<p>Adhere the patch in such manner that all of the patch is covered by using the hypoallergenic tapes.</p>

NOW THE PATIENT SHOULD REST ON BED IN SUPINE POSITION FOR 24 HOURS.