Qualitative and quantitative composition
Active substance: sodium hyaluronate.
Excipients: succinic acid, sodium succinate, sodium chloride and water for injection.

Classification of the product
Medical device – sterilized and pyrogen-free- Class III.

Package
1 ml pre-filled disposable syringe which contains 1.1 % (11mg) of hyaluronic acid.
2 ml pre-filled disposable syringe which contains 1.1 % (22mg) of hyaluronic acid.
1 ml pre-filled disposable syringe which contains 1.8 % (18mg) of hyaluronic acid.
2 ml pre-filled disposable syringe which contains 1.8 % (36mg) of hyaluronic acid.

⚠️ Only contents of the syringe is sterile. The medical device has been sterilized by steam sterilization.

⚠️ Each Package contains:
- Two Hypodermic needles (0,80x50mm – Manufactured by Becton Dickinson and Company Limited - CE 0050)
- for the injection of the medical device.
- Two labels with variable data of the product (LOT number and EXP. date).

Indications
Hyaluronic acid is a natural polysaccharide and an important building block of the skin and connective tissues. DIART® has the form of gel; it is sterile, pyrogen-free, colorless and transparent hyaluronic acid of non-animal origin with optimum pH.

Medical device DIART® is intended to be injected in joints in order to temporarily restore the viscoelasticity of synovial fluid of the joints in the case of problems due to trauma or diseases such as osteoarthritis.

Warnings and special precautions for use
- Do not administer intravenously.
- Do not use if the solution is not transparent and colorless.
- Do not use if the package is opened or damaged.
- The product must be used immediately after opening and destroyed once it has been used.
- Do not reuse. Once the product has been used for the first time, any residuals of the product are not suitable for the repeated use as the product is no longer sterile.
- Do not resterilize. Repeated sterilization may cause cross-contamination for the patient and the surgeon.
- Do not insert air in the syringe.
- Do not freeze.
- Heating in a microwave oven is not recommended.
- Solution must not be administered orally.
- The product is intended for single use. After the first injection, the unused product is no longer sterile. Do not use product residuals.
- Before treatment, perform a slight pressure on the syringe plunger in order to create a drop on the needle tip, thus eliminating any air bubbles present in the product.

Special directions
- You should always observe the aseptic techniques when using the medical device.
- Do not use the device on patients with known hypersensitivity to any of the product components.
- Do not use in patients who have suffered in the last two weeks thrombolytic therapy or anticoagulant therapy.
- Do not use in patients with symptoms of viral or bacterial infections or similar.
- Do not use together with disinfectants containing quaternary ammonium salts, such as benzalkonium chloride, for the preparation of the skin.
- Do not heat or cool the injection point before the disappearance of redness or edema due to primary treatment.
- Do not use the product in the presence of infections or serious infections or skin diseases or skin infections in the injection site.
- Do not use in patients less than 18 years.
- Do not use this product on patients who are pregnant or breastfeeding.

Adverse reactions and side effects
Like any routine involving other injectable product, this medical procedure may cause discomfort in some patients.
Skin rash (redness, swelling, edema, bruising, itching and minor pain at the site of injection) may occur as a result of the medical procedure. Usually these symptoms regress within 72 hours.
In rare cases, signs of solidification and temporary loss of sensation at the site of injection may appear.
In very rare cases described in the literature, signs of necrosis, papilla, granulomas, hypersensitivity and abscess formation may occur after the injection with hyaluronic acid-based products.
In the event of any of the mentioned cases, immediately contact your doctor and the manufacturer of the medical device.
Route of administration and dosage
DIART ® should only be administered by health care professionals trained in the intra-articular injection techniques and should only be administered into the synovial space. Before treatment, it is necessary that the operator is informed about the medical history of the patient and it is necessary that the same informs the patient of the expected outcome of treatment and potential side effects.
DIART ® may be administered for a period of 3-5 weeks with 1-2 weeks interval between one treatment and the other, depending on the severity of the problem. DIART ® is supplied in 1 ml or 2 ml syringes to be used based on the size of the injection site. The recommended treatment regimen is 3 intra-articular injections per joint. The treatment regimen may be repeated after 6 months from initial treatment, if warranted by the patient’s symptoms and if prescribed by your doctor.

How to use
- Check the expiration date indicated on the package. Do not use after the expiry date.
- Attach the label with the product data (batch number and expiry date) to the Medical Record of the patient who will undergo the procedure.
- Open the sterile package.
- Remove the stopper plug from the syringe connector.
- Attach the needle to perform the procedure. Make sure that the needle is properly attached to the syringe.
- Remove the cover of the needle.
- Before treatment, perform a slight pressure on the syringe plunger to create a drop on the needle tip, thus eliminating any air bubbles present in the product.
- Give the injection and carry out the medical procedure.
- Once the product has been used, discard it pursuant to the current state regulations.

Shelf life
2 years in an intact package.

How to store
Store at the temperatures from 5 °to 30 °C (included), away from direct light and heat, in the adequately closed packaging.
The expiry date is applied to the product which is correctly stored in an intact package.

<table>
<thead>
<tr>
<th>DIACO BIOFARMACEUTICI Srl Via Flavia 124, 34147 – Trieste (TS) Italy</th>
<th>Symbols used on the packaging and box labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Do not reuse – for single use</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td></td>
<td>Expiry date</td>
</tr>
<tr>
<td></td>
<td>Do not use if the package is opened or damaged</td>
</tr>
<tr>
<td></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td></td>
<td>Medical device according to Directive 93/42/ CEE</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Symbols used on the packaging and box labels