Technical Data Sheet

# **MoliCare® Premium Form**, incontinence pad

**General Product Description/Intended Purpose**

**Intended Purpose:**

MoliCare® Premium Form products are absorbent pads for incontinence care. The products are, in combination with fixation systems, suitable for usage in case of bladder weakness with several severities, urinary and faecal incontinence with several severities.

The MoliCare® Premium Form products are intended for mobile to immobile patients (women and men).

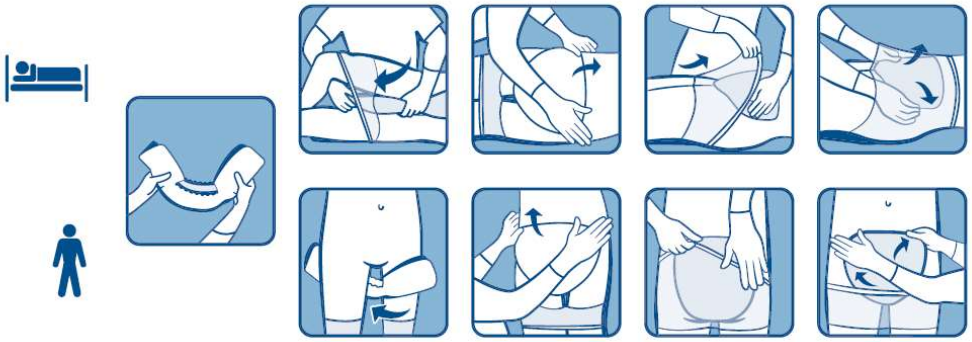
MoliCare® Premium Form MEN are intended for mobile to immobile patients (men).

The products are for single use only and should be regularly changed as needed.

MoliCare® Premium Form products can be used in home care environment and professional healthcare facilities. The application can be performed by lay person and/or health care professional.

**Application/Indication**

Several severities of urinary and faecal incontinence



**Reference Numbers***

| Packaging | P30 | P28 | P14 | Display (P30) | P2 |
|---|---|---|---|---|---|
| **normal (3 drops)** | 168 119 | 168 118 | - | - | 168 074 |
| **normal plus (4 drops)** | 168 019 | 168 018 | - | 168 110 / 168 179 | 168 174 |
| **extra (5 drops)** | 168 219 | 168 218 | - | 168 210 / 168 279 | 168 274 |
| **extra plus (6 drops)** | 168 319 | 168 318 | - | 168 310 / 168 379 | 168 374 |
| **super (7 drops)** | 168 719 | 168 718 | - | 168 720 | 168 474 |
| **super plus (8 drops)** | 168 919 | 168 918 | - | 168 410 /168 579 | 168 574 |
| **maxi (9 drops)** | - | - | 168 619 / 168 618 | - | 168 674 |
| **MEN (6 drops)** | - | 168 819 / 168 818 | - | - | 168 774 |

*the full assortment may not be available in all countries

**Single use Device**

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request. Reuse of the product could lead to microbiological contamination and/or mild infections of the skin.

# MoliCare® Premium Form, incontinence pad

### Product disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of MoliCare® Premium Form should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

### Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

### Product performance characteristics

| Characteristics | unit | normal (3 drops) | normal plus (4 drops) | extra (5 drops) | extra plus (6 drops) | super (7 drops) | super plus (8 drops) | maxi (9 drops) | MEN (6 drops) |
|---|---|---|---|---|---|---|---|---|---|
| **total weight:*** | **[g]** | **51** | **59** | **64** | **94** | **99** | **106** | **129** | **94** |

*≤ ± 10% tolerance

### Material characteristics

| Part | Material |
|---|---|
| back sheet: | polyethylene, nonwoven-film-laminate, white |
| absorbent core (3-layer): | 1. layer: kraft pulp*<br>2. layer: kraft pulp*- with superabsorbent polymer<br>3. layer: kraft pulp*, „Curled Fiber“<br>*bleached elementary chlorine free |
| adhesive: | hotmelt adhesive |
| top sheet: | polypropylene - nonwoven, hydrophilic, white |
| cuff: | polypropylene - nonwoven, hydrophobic, white |
| elastics: | elastics for leg gather and standing cuffs |
| wetness indicator: | water soluble ink |

### Product characteristics

| Dimensions | normal (3 drops) | normal plus (4 drops) | extra (5 drops) | extra plus (6 drops) | super (7 drops) | super plus (8 drops) | maxi (9 drops) | MEN (6 drops) |
|---|---|---|---|---|---|---|---|---|
| total length:* | 525 | 620 | 620 | 690 | 690 | 690 | 690 | 690 |
| total width abdominal side:* | 260 | 280 | 280 | 300 | 300 | 300 | 300 | 310 |
| total width back side* | 280 | 295 | 295 | 310 | 310 | 310 | 310 | 310 |
| total width crotch:* | 210 | 235 | 235 | 245 | 245 | 245 | 245 | 245 |
| absorbent core length:* | 474 | 560 | 560 | 630 | 630 | 630 | 630 | 630 |
| absorbent core width abdominal side:* | 215 | 240 | 240 | 250 | 250 | 250 | 250 | 270 |
| absorbent core width back side:* | 242 | 255 | 255 | 260 | 260 | 260 | 260 | 260 |
| absorbent core width crotch:* | 134 | 160 | 160 | 170 | 170 | 170 | 170 | 160 |

*≤ ± 10% tolerance

# **MoliCare® Premium Form**, incontinence pad

**Labelling**

9-digit LOT-code
e.g.: 900102822

| LOT | 9 | 001 | 02 | 82 | 2 |
|---|---|---|---|---|---|
| | year 201X | internal key | internal key | internal key | cumulated check sum |

Manufacturing date

| e.g.: | 2019 year | 08 month | 07 day |
|---|---|---|---|

Expiry date

| e.g.: | 2024 year | 08 month | 01 day |
|---|---|---|---|

Shelf life: 5 years

Medical Device

MD

Keep dry

Do not reuse

CE-marking

CE

**Latest date of revision:** 2020-06-16