

13. Washing instructions

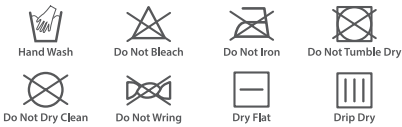
Please follow the washing instructions below to maintain the longevity of your garment, a copy of which is printed on the silk label sewn into your gaiter.

Wash your garment separately for the first time to avoid any colour run. We recommend closing any hook-and-loop fastenings prior to washing as this helps to protect and prolong the life of your garment.

TIP: After hand washing, tightly roll your garment inside a thick towel to remove excess moisture, then dry flat on a second dry towel.

Key points to note:

- Wash dark colours separately
 - DO USE a non-biological mild detergent
 - Please do not use a fabric conditioner
 - Please do not dry in direct sunlight
 - Please do not dry on a radiator
 - Please do not dry in a tumble dryer
 - When hand washing, please rinse well and do not wring
- We advise that Medigarments gaiters are washed 1-2 days a week to help rejuvenate the fabric.



15. Definition of Symbols

- Read instructions before use
- Manufacturer name and address
- Date of manufacture
- EC REP, European Authorised Representative to represent Medigarments Ltd in the EU and ensure compliance with the European Directives
- Medical Device
- CE marking
- UK Conformity Assessed marking
- Single Patient Use, do not share this garment
- Patient number
- Keep Dry
- Protect from Sunlight
- Disposal in household waste

16. Storage and shelf life information

Please store your new gaiter in a dry place away from direct sunlight. Do not place near any heat source. Do not leave inside a car in hot weather.

Medigarments gaiters are designed for immediate use as body measurements may change over time.

With the correct handling and care, your garment may last for up to 6 months repeated wearing (usage period), after which time you will need to consult your medical professional to be measured for a new garment.

Please contact your treating clinician if the following occurs:

- You gain or lose a significant amount of weight
 - Your condition changes
 - Your garment has degraded and needs to be replaced
- Should the above conditions apply, a new garment may be required before the 6 month period has elapsed. Please do not wear a garment that is too tight or too loose as this can cause delays in your therapeutic success.

Your new gaiter is intended for your usage only, please do not give this garment to a third party.

17. Disposal of your garment

There are no specific instructions for garment disposal. Please dispose of your used garments in your household waste or clothing recycling bank.



Medigarments Ltd

DESIGNED AROUND YOU

Gaiters Instructions For Use



Medigarments Ltd
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Contents

Please keep this leaflet in a safe place as you may need to refer to it again. If you have any questions that have not been covered in this leaflet or are not sure about anything, please ask your treating clinician for guidance.

This leaflet contains details about the following:

1. Intended Use
2. When to wear your gaiter
3. Donning your gaiter
4. Types of gaiter available
5. Indications
6. Contraindications
7. Existing medical conditions
8. Warnings and Precautions
9. In case of serious incident
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1. Intended use

Medigarments gaiters are available as made-to-measure and off-the-shelf external devices that feature structural inserts which immobilise the joint to hold it in extension and/or optimal position whilst preventing excessive movement. Gaiters can be worn on either the arms or legs to keep the elbows or knees straight and stabilised. Full circumference hook and loop straps are used to secure the gaiter around the limb.

Medigarments gaiters are made from a flexible material and stiffened with bones or stays to limit movement. The reasons behind your immobilisation can vary and your treating clinician will be able to explain this fully. Gaiters are suitable for use on all four limbs and can be used by infants through to adulthood. All of our gaiters should be assessed and prescribed by a suitably qualified clinician who is able to review and reassess as needed.


Your new Medigarments gaiter has been expertly designed and manufactured in Long Eaton, Nottingham in the UK.

2. When to wear your gaiter

Please note made-to-measure gaiters have been expertly measured and designed for the user and must be worn by the user only. It must not be applied to anyone else. Ready-to-wear gaiters are not patient dependent but are designed for a single user.

The gaiter should offer a snug fit and can be expected to cause red marks initially. These soft tissue marks should disappear within 15-30 minutes of removing the garment. If the marks persist for longer than 30 minutes do not increase the wearing time and inform your treating clinician directly.

You should ensure your garment is regularly reviewed by your treating clinician. Should your condition change during the life cycle of your gaiter, please contact your treating clinician immediately as the performance of the device may be affected. Should you develop any sores or blisters you should stop use of the device at once.

 **This device should be recommended and periodically checked by a suitably qualified person only**

3. Donning your gaiter

Please follow the advice of your treating clinician before you wear this gaiter.

For all gaiters, please follow the standard instructions below:

- Read through this instruction booklet, paying particular attention to section **8. Warnings and Precautions** and **12. Additional Information** before wearing your new gaiter
- Avoid using your gaiter if you have any acute skin rashes or if a vascular/circulation problem arises until cleared by your treating clinician

Fitting Instructions:

- Check the gaiter straps are free from debris and move/function freely
- Undo all the hook and loop fastenings and place on a stable surface with the lining facing upwards. Ensure the top (widest) part of the gaiter is closest to you

- Carefully straighten the limb and place onto the gaiter, ensure the narrow part of the gaiter is in line with the wrist or ankle
- Fold the gaiter around the limb ensuring that the 'tongue' is flattened out beneath the overlapping edge
- Fasten the hook and loop fastener straps securely but do not over tighten the gaiter. The gaiter should be a comfortable garment to wear and not restrict circulation
- Straps may be shortened as required by cutting between the stitched lines at the ends of the straps

4. Types of gaiter available

Ready-to-wear Gaiters

- Extension Arm/Leg Gaiter

Made-to-measure Gaiters

- Extension Arm/Leg Gaiter
- Flexion Arm/Leg Gaiter

5. Indications

- Flexion Contractures
- Post-Surgery
- Juvenile Rheumatoid Arthritis (JRA)
- Sprains, strains or weakened joints
- Post-Injury
- Dislocations
- Post-Fracture
- Support during the night

6. Contraindications

- Flexion angles greater than 80°
- Skin irritations or ulcerations

7. Existing Medical Conditions

Your treating clinician should be made aware of any existing medical conditions you may have so this can be considered when prescribing your gaiter. If you have not alerted your clinician to any of the conditions below, please **DO NOT** wear this garment until your clinician confirms it is safe to do so. Existing medical conditions include but are not limited to:

- Certain skin conditions e.g. Eczema
- Vascular/Circulation problems
- Oedema
- Weight fluctuations
- Epilepsy

8. Warnings and Precautions

There are no known side effects when wearing this garment in the correct manner as directed by your clinician or GP. If your medical condition deteriorates whilst wearing this garment, please consult your doctor or clinician immediately.

The manufacturer is not liable for any damages, conditions or injuries that occur from handling or using this garment incorrectly. This includes any alterations or tampering by the user. Your gaiter must be regularly maintained to the maintenance schedule in this IFU.

Gaiters are not flame retardant, please avoid naked flames when wearing.

Please stop wear and contact your treating clinician if any of the below occur:

- Allergic reaction

- Discolouration or a change in body temperature showing circulation or vascular problems
- Lasting redness, skin abrasions or blisters
- Raised temperature

If you have any open wounds in the area to be treated, these need to be covered with an appropriate wound dressing or bandage, before the garment can be applied.

9. In Case of Serious Incident

In the event of a serious incident that may result in the deterioration of a patient's medical condition or may risk death, **STOP** using your garment immediately and contact:

- The manufacturer Medigarments Ltd.
- The relevant authority in the Member State
- The UK Medicines and Healthcare products Regulatory Agency (MHRA)

In the event of manufacturing faults such as damage to the fabric and stitching or if you have any concerns regarding the fitting of your garment, please contact your treating clinician immediately.

10. Latex

This garment does not contain latex.

11. Fabric composition

The fabric composition is printed on the silk label inside your garment.

12. Additional information

Please follow instructions provided by your treating clinician and wear as directed to achieve optimum results. You may have to seek help with donning and doffing your garment and your clinician should be made aware of this. Always check garment and skin daily before use. Do not use if you have hypersensitivity or an allergic response to the garment materials. Please report to your treating clinician urgently. When re-applying your garment after bathing, creaming and massaging, make sure the skin is dry and no residue cream remains on the skin.

Gaiters are not suitable for extreme sports, running or cycle racing, ice and snow sports, extreme slopes and steps. Any such activities undertaken are done so completely at the users' own risk. Always use a handrail when descending stairs and at any other time if available. This gaiter is not intended to be used in water or whilst showering.

All persons are required to observe their respective driving laws when operating motor vehicles. It is the responsibility of the user to discuss this matter with the DVLA.

Repairs and adjustments to your gaiter must be carried out by Medigarments Ltd. If you have any problems with the device please contact your treating clinician as soon as possible.

Important: Please do not remove the silk label within your garment as the warranty will be void.