

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 Sensory Hug®.

Wash your garment separately for the first time to avoid any colour run. We recommend closing any zips and 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 your Sensory Hug® is washed 2-3 days a week to help rejuvenate the fabric.



Medigarments Ltd
DESIGNED AROUND YOU

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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 Sensory Hug® in a dry place away from direct sunlight. Do not place near any heat source. Do not leave inside a car in hot weather.

Sensory Hug® garments 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 12 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 12 month period has elapsed. Please do not wear a garment that is too tight or too loose as this can cause undue stress and anxiety.

Your new Sensory Hug® garment 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.



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Sensory Hug® Instructions For Use



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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 Sensory Hug®
3. Donning your Sensory Hug®
4. Types of Sensory Hug® available
5. Indications
6. Contraindications
7. Existing medical conditions
8. Warnings and Precautions
9. In case of serious incident
10. Latex
11. Fabric composition
12. Medigarments Ltd address details
13. Washing Instructions
14. Additional information
15. Definition of symbols
16. Storage and shelf life information
17. Disposal of your garment

1. Intended use

The Sensory Hug® is intended to provide sensory and proprioceptive feedback through dynamic compression. The Sensory Hug® aims to enhance the function of the wearer and help normalise activities of daily living by providing consistent and continuous deep pressure. Sensory Hug® garments may also help to reduce over-activity and abnormal behaviour patterns in individuals with sensory processing difficulties. Your new Sensory Hug® has been designed and manufactured in Long Eaton, Nottingham in the UK.

2. When to wear your Sensory Hug®

It is the responsibility of the user/parent/carer or in cases of being prescribed, the treating clinician or GP to monitor the Sensory Hug® garment and decide when a new garment is required. It is advised that your garment is reviewed every 4-6 months to accommodate for any changes. The Sensory Hug® should offer a snug fit and may cause red marks initially (most commonly around the shoulders, armpits and under the seams). These soft tissue marks should disappear within 30-40 minutes of removing the garment. If the marks persist for longer than 30-40 minutes the garment may require adjusting.

Medigarments Ltd have supplied each Sensory Hug® with 3 additional zip strips that increase or decrease the pressure. Please adjust your garment until the desired compression is achieved. If the garment is still too tight after adding all 3 zip strips, then a new garment at a larger size is required.

As the name suggests, the garment has to provide the necessary compression to meet the needs of the user and may require some time to build up tolerance to wearing.

Wearing Schedule:

On the first day of wear the Sensory Hug® should be worn for a maximum of two hours at any one time. If after two hours there are no adverse reactions then increase the next wearing time by one hour

- Please discuss maximum daily time in the garment with your prescribing clinician. If the garment is overused then the patient may not get the optimum sensory input when needed
- It is advised that you should not sleep in the Sensory Hug®
- To obtain maximum benefit from the Sensory Hug® garment we advise wearing the garment when undertaking any activities that require concentration, such as eating and studying, or to calm and comfort an individual in times of anxiety (unless any adverse effects/contraindications/precautions are identified)

3. Donning your Sensory Hug®

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

For all Sensory Hug® garments, please follow the instructions below:

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

- Check the Sensory Hug® straps are free from debris and move/function freely

Fitting Instructions:

- Undo all of the hook and loop fastenings on the garment and remove excess zip strips
- **Sensory Hug® Mini** - Ensure shoulder poppers are fastened at their loosest setting and place over the head
- **Sensory Hug® Maxi** - Wrap the garment around the waist and place straps loosely over the shoulders
- Fasten the zip, take care not to catch the skin when fastening
- If the garment is too tight or will not fasten, add in one of the additional zip strips, add more if required up to the maximum 15cm with all 3 strips combined
- **Sensory Hug® Mini** - Adjust shoulder poppers for comfort.
- **Sensory Hug® Maxi** - Pull each shoulder strap under the armpit and secure around the opposite side of the waist using the hook and loop fastenings
- Tighten as required but do not over tighten and restrict circulation
- Fasten rear straps and adjust all straps for desired comfort

4. Types of Sensory Hug® available

- Sensory Hug® Mini
- Sensory Hug® Maxi

5. Indications

Sensory processing difficulties such as Autism, ADHD/ADD and SID/SPD

6. Contraindications

- Skin irritations
- Dislocated joints (not reduced)
- Skeletal conditions
- Open Wounds/ulcerations
- Contractures/Soft tissue shortening

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 purchasing your Sensory Hug®. 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 treating clinician or GP. If your medical condition deteriorates whilst wearing this garment, please consult your clinician or GP 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 Sensory Hug® must be regularly maintained to the

maintenance schedule in this IFU.

Sensory Hug® garments are not flame retardant, please avoid naked flames when wearing.

Please stop wear and contact your treating clinician or GP 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 prescribed to achieve optimum results. You may have to seek help with donning and doffing your garment and your treating clinician should be made aware of this. The Sensory Hug® can be worn under or over clothing.

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 or GP 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.

Sensory Hug® garments 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. The Sensory Hug® is not intended to be used in water or whilst showering.

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