

Instructions For Use

ComfiKIDS™ Ready to Wear Garments



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Information

This instruction for use document is designed to provide a comprehensive source of information for the safe and effective use of Vernacare Limited ComfiKIDS™ ready to wear child garments. Please retain and consult this document before, during and after the use of this product. The following conventions are used throughout this document:



























WARNING highlights a safety related issue


CAUTION highlights product functionality information



NOTE supplements and/or clarifies procedural information

In the event of a serious product related incident or to request additional product information please visit our website or please contact us on **+44 (0)1204 529494** or visit **vernacare.com**

Symbol Glossary

	Indicates Compliance with relevant EU Medical Device Legislation		Do not use if packaging is damaged		Indicates the product expiry date
	Indicates that the device is a medical device as defined in the MDR (2017/745)		Contains hazardous substances		Date of manufacture
	Indicates the authorised representative within the European Community		Keep product out of direct sunlight		Consult Instructions For Use
	Indicates the authorised representative within the country Switzerland		Keep dry		Product does not contain latex
	Manufacturer (the person placing the device on the market)		Indicates Compliance with relevant UK Medical Device Legislation		Product contains latex
	Indicates a warning notice in the text		Product is supplied sterile by Ethylene Oxide		Single patient multiple use
	Product is for single use only and must not be re-used or re-processed		USA Federal Law Restricts this device to sale by, or on the order of, a physician		Fragile, handle with care
	Do not re-sterilize		Indicates the manufacturer's batch number		Temperature limits to which the medical device can be safely exposed
	Non-sterile product		Manufacturers reference number for the product		

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Instructions For Use

ComfiKIDS™ Ready to Wear Garments



Product Description

ComfiKIDS™ ready to wear garments.



Product Codes

CC14, CC5, CL11, CL14, CL5, CL8, CM14, CM24, CM8, CS14, CS8, CT24, CV5, CV8, CV11, CV14, CV24.

Intended Use

Wet and dry wrapping for atopic eczema, preventing staining of clothes when using topical treatments, retaining stump dressings, and dressing retention.

Material Composition

Viscose, elastane, polyamide.

Important Warnings



- Please read and understand the contents of this document and the product packaging prior to use.



- Prior to use, please ensure the product and its packaging is not damaged and suitable for use.



- Keep the garment away from fire.
- Product is designed for single patient reuse only. Do not place a used/washed tubular bandage onto another patient.

- Must only be worn for 24 hours, and then washed before being applied again. Please refer to washing instructions.

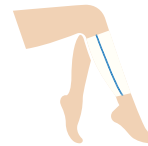


- This product is not manufactured with natural rubber latex
- If irritation/sensitisation occurs on or around the site of application of the tubular bandage, please remove the bandage immediately and consult a healthcare professional.

Contraindications

- The devices in this product range are not compression bandages and must not be used as such.
- ComfiKIDS™ ready to wear garments must not be applied directly to open wounds.

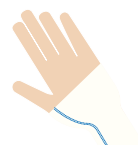
Indications For Use



Dressing retention



Eczema, dry skin & psoriasis



Covering fragile skin

Intended Users

Intended to be used on children between the ages of 6 months to 14 years, depending on the width of the garment. No special training is required to use this device however, prior to use please consult a healthcare professional.

Shelf Life

5 years from date of manufacture.

Maintenance of Device

The device requires no calibration and is ready to use upon opening of the packaging. The device can be washed a per the following washing instructions.

Wash at 60°C. Do not bleach. Do not dry clean. Tumble dry on low heat. Do not iron. We recommend that ComfiKIDS™ ready to wear garments should not be washed more than 5 times. Do not use the device if the material becomes frayed.

Instructions For Use

Dressing Retention

1. Measure Circumference of the affected area at the widest point.
2. Choose the correct size of ComfiKIDS™ ready to wear garments.
3. Place the bandage over the affected area.

Dry Wrapping

The decision to dry wrap should only be taken by an appropriately qualified healthcare professional.

1. Bathe and pat dry the skin and then apply emollient to the skin, as directed by a healthcare professional.
2. To apply as a dry wrap follow steps 1-4 in the "Dressing Retention" section.

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Wet Wrapping

The decision to wet wrap should only be taken by, and under the direct supervision of, an appropriately qualified healthcare professional.



Do not wet wrap if eczema appears wet or infected, or if the end user/patient is generally unwell.

Vernacare make no recommendations onto what emollient to use during this treatment.

1. Two layers of the ComfiKIDS™ ready to wear garments are required – one wet and one dry.
2. Bathe and pat dry skin and then apply emollient to the skin, as directed by a healthcare professional.

3. Choose the correct size of ComfiKIDS™ ready to wear garments and cut to length required (refer to “Product Selection Guide” below).
4. Soak the first layer of ComfiKIDS™ ready to wear garments in warm water axbular bandage applicator into the bandage and apply wet bandage.
6. Apply a dry layer of ComfiKIDS™ ready to wear garments over wet layer, following steps 1-4 in the “Dressing Retention” section.



Storage Conditions

Cool dry environment away from direct sunlight.

Disposal of the Device

No special disposal routes.



Product Selection Guide

Product	Size : Limb Circumference	REF	NPC
Child Vest	6 - 24 months	CV24	EGC014
	2 - 5 years	CV5	EGC015
	5 - 8 year	CV8	EGC016
	8 - 11 years	CV11	EGC017
	11 - 14 years	CV14	EGC018
Child Tights	6 - 24 months	CT24	EGC022
Child Leggings	2 - 5 years	CL5	EGC023
	5 - 8 years	CL8	EGC024
	8 - 11 years	CL11	EGC025
	11 - 14 years	CL14	EGC026
Child Clava	6 months - 5 years	CC5	EGC012
	5 - 14 years	CC14	
Child Mittens	Up to 24 months (with thumb hole)	CM24	EGC019
	8 years (with thumb hole)	CM8	EGC020
	8-14 years (without thumb hole)	CM14	EGC021
Child Socks	up to 8 years	CS8	EGC027
	8-14 years	CS14	EGC028



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