

TENDERWRAP - zinc oxide, calamine dressing
Tyco Healthcare Group LP

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredients

Zinc Oxide 25%

Calamine 1%

Purpose

Skin Protectant

Uses

- Dries the oozing and weeping of poison ivy, poison oak, or poison sumac.
- Ideal for the managing extremities (e.g. varicose ulcers) requiring protection and support.

Warning

- **Keep out of reach of children.**
- For external use only.
- When using this product do not get into eyes.
- Stop use and ask a doctor if:
 - conditions worsens
 - symptoms last more than 7 days
 - clear up and occur again within a few days.

Directions

- Begin bandaging at base of toes, without pressure, keeping foot and leg at right angle.
- Continue bandaging beyond ankle, doubling back to ensure molding to contours of the leg.
- Complete bandaging to just below the knee and apply an adhesive elastic bandage to secure the Unna Boot.
- Re-apply as needed

Other Ingredients

Acacia, Castor oil, Glycerin, and White Petrolatum.

Principal Display Panel

NDC 12823-401-35

REF **8035**

tyco/Healthcare

KENDALL

TENDERWRAP TM

Unna Boot Bandage
with Calamine

3 in (7.5 cm) x 10 yd (9 m)

Unna underbensbandage
med zinkliniment

Unna Boot verband met
calamine

Ligadura de pe Unna
com Calamina

Bandage pour botte d'Unna
a la calamine

Zinkleimverband mit
kieselzinkerz

Fasciatura a stivaletto Unna
con calamina

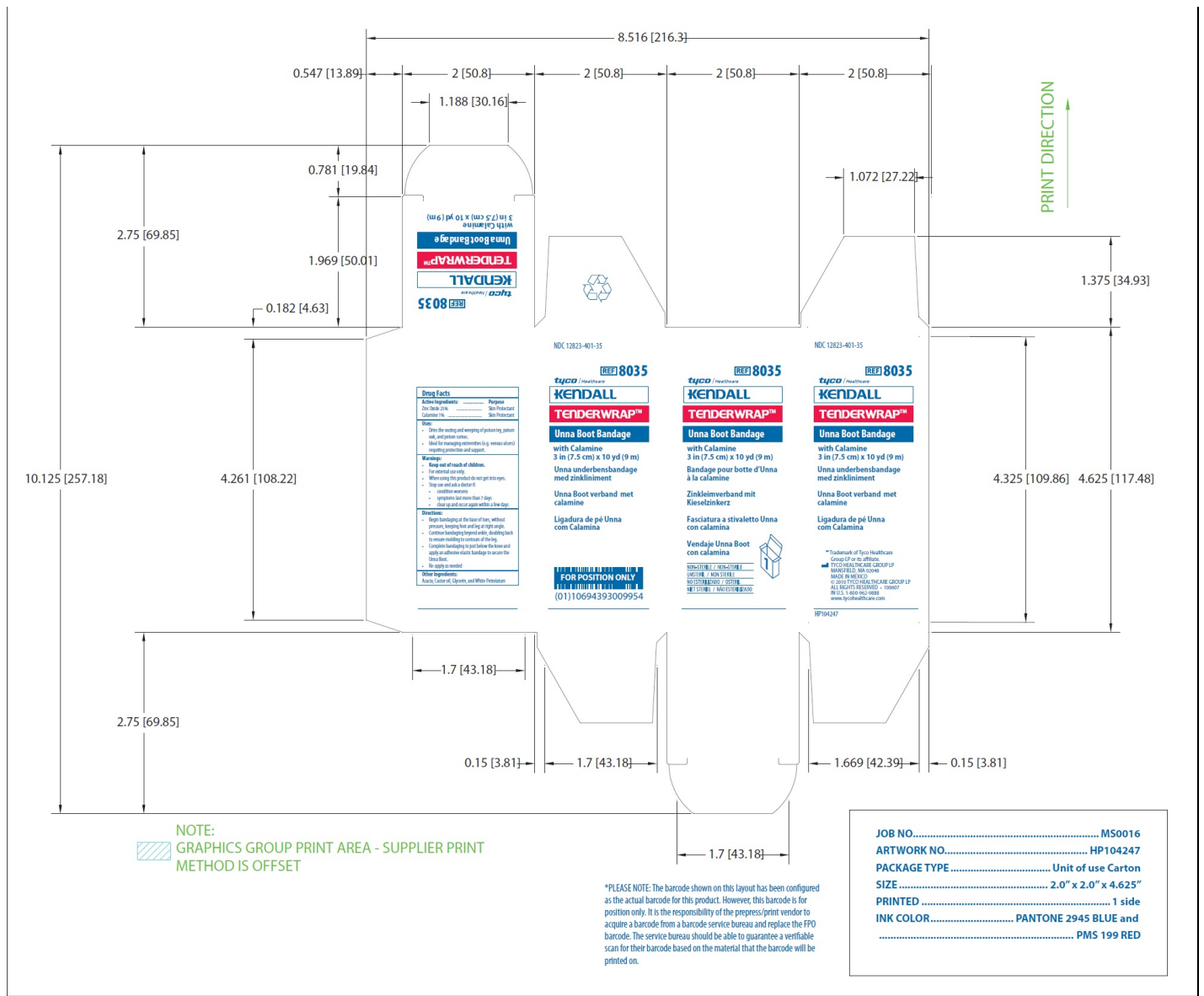
Vendaje Unna Boot
con calamina

NON-STERILE / NON-STERILE
UNSTERIL / NON STERILE
NO ESTERILIZADO/ OSTERIL
NIET STERIEL / NAO ESTERILIZADO

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TYCO HEALTHCARE GROUP LP
MANSFIELD, MA 02048
MADE IN MEXICO

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www.tycohealthcare.com



NDC 12823-401-36

REF 8036

tyco/Healthcare

KENDALL

TENDERWRAP™

Unna Boot Bandage
with Calamine

4 in (10 cm) x 10 yd (9 m)

Unna underbensbandage

med zinkliniment

Unna Boot verband met
calamine

Ligadura de pe Unna
com Calamina

Bandage pour botte d'Unna
a la calamine

Zinkleimverband mit
kieselzinkerz

Fasciatura a stivaletto Unna
con calamina

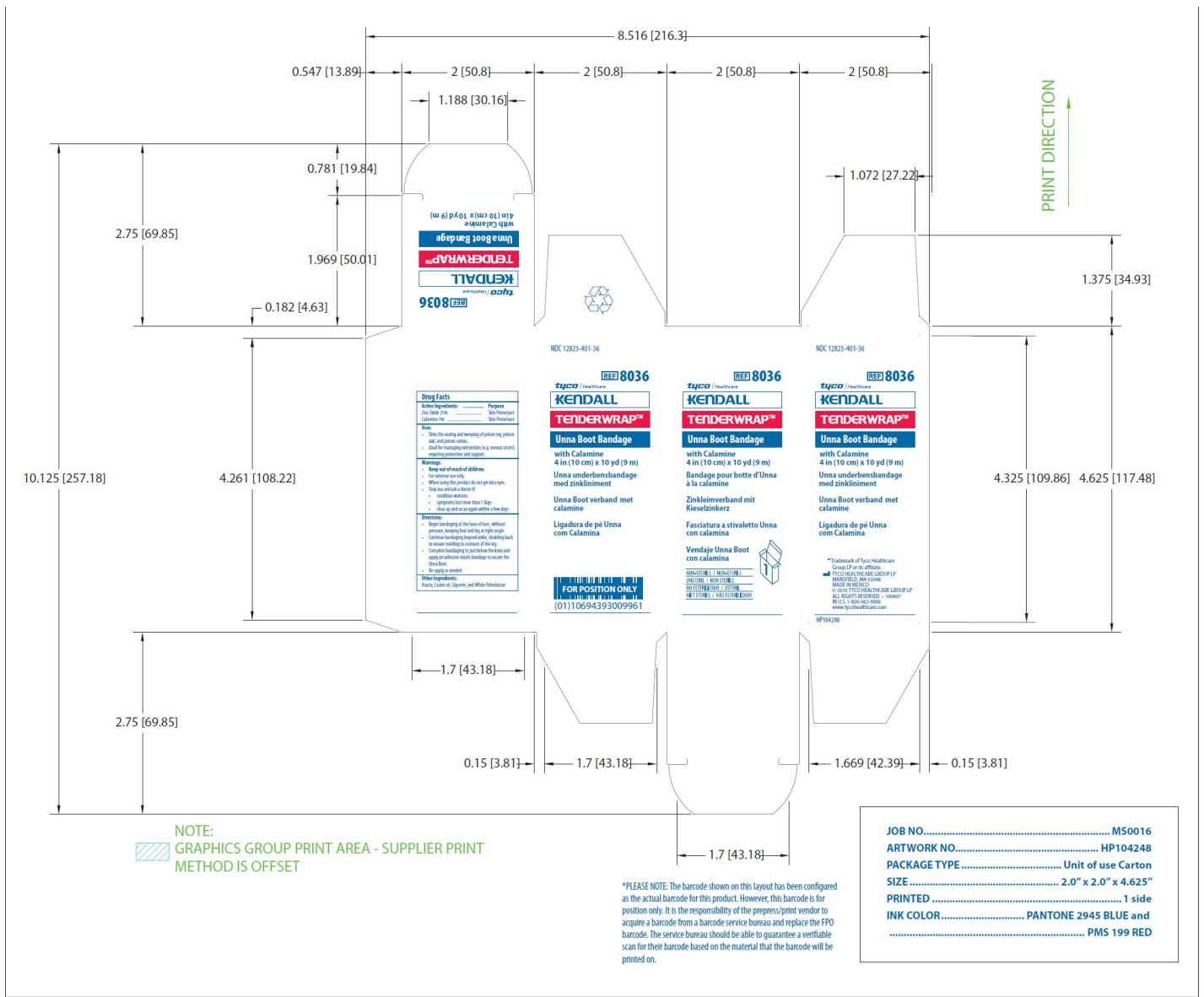
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TENDERWRAP

zinc oxide, calamine dressing

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:12823-401 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--------------------------------------------------------------------------|-------------------|----------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC OXIDE | 25 g |
| FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675) | FERRIC OXIDE RED | 0.015 g |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC OXIDE | 0.985 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-------------------------------|----------|
| ACACIA (UNII: 5C5403N26O) | |
| CASTOR OIL (UNII: D5340Y2I9G) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:12823-401-36 | 1 in 1 BOX | | |
| 2 | NDC:12823-401-35 | 1 in 1 BOX | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | part347 | 07/29/2010 | |

Labeler - Tyco Healthcare Group LP (048696421)

Revised: 7/2010

Tyco Healthcare Group LP