CORTIZONE 10 COOLING RELIEF- hydrocortisone gel CORTIZONE 10- hydrocortisone cream CORTIZONE 10 INTENSIVE HEALING- hydrocortisone cream CORTIZONE 10- hydrocortisone ointment CORTIZONE 10 PLUS- hydrocortisone cream Chattem, Inc.

Cortizone-10

Cortizone-10® Cooling Relief Gel

Active Ingredient:

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - · insect bites
 - detergents
 - jewelry
 - cosmetics
 - soaps
 - · seborrheic dermatitis
 - temporarily relieves external anal and genital itching
 - other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- · rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for itching of skin irritation, inflammation, and rashes:
 - adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

- children under 2 years of age: ask a doctor
- for external anal and genital itching, adults:
 - when practical, clean the affected area with mild soap and warm water and rinse thoroughly
 - gently dry by patting or blotting with toilet tissue or a soft cloth before applying
 - apply to affected area not more than 3 to 4 times daily
 - children under 12 years of age: ask a doctor

Other information

• contents filled by weight, not volume

Inactive Ingredients

aloe barbadensis leaf juice, avena sativa (oat) kernel extract, cyclopentasiloxane, dimethicone, dimethicone/vinyl dimethicone crosspolymer, disodium EDTA, glycerin, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, maltodextrin, menthyl lactate, methyl gluceth-20, methylparaben, polysorbate 60, propylparaben, SD Alcohol 40-2 (15%), sodium citrate, water

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*Refers to the ingredient hydrocortisone

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www.ditchtheitch.com 0042740-02

Cortizone-10® Creme

Active Ingredient:

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - · insect bites
 - detergents
 - jewelry
 - cosmetics
 - soaps
 - seborrheic dermatitis
 - temporarily relieves external anal and genital itching
 - other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor.
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for itching of skin irritation, inflammation, and rashes:
 - adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
 - · children under 2 years of age: ask a doctor

• for external anal and genital itching, adults:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

contents filled by weight, not volume

Inactive Ingredients

aloe barbadensis leaf juice, aluminum sulfate, beeswax, calcium acetate, cetearyl alcohol, dextrin, glycerin, maltodextrin, methylparaben, mineral oil, petrolatum, propylparaben, sodium cetearyl sulfate, sodium lauryl sulfate, water

*Refers to the ingredient hydrocortisone

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www.chattem.com 0040433-02

Minor change

Cortizone-10® Creme Intensive Healing Formula

Active Ingredient:

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - · insect bites
 - detergents
 - jewelry

- cosmetics
- soaps
- · seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor.
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- · rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for itching of skin irritation, inflammation, and rashes:
 - adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
 - children under 2 years of age: ask a doctor

· for external anal and genital itching, adults:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

contents filled by weight, not volume

Inactive Ingredients

water, glycerin, dimethicone, petrolatum, jojoba esters, cetyl alcohol, aloe barbadensis leaf juice, stearyl alcohol, distearyldimonium chloride, cetearyl alcohol, steareth-21, steareth-2, polysorbate 60, stearamidopropyl PG-dimonium chloride phosphate, methyl gluceth-20, chamomilla recutita (matricaria) flower extract, tocopheryl acetate, magnesium ascorbyl phosphate, hydrolyzed collagen, hydrolyzed elastin, retinyl palmitate, hydrolyzed jojoba esters, glyceryl stearate, EDTA, PPG-12/SMDI copolymer, potassium hydroxide, avena sativa (oat) kernel extract, menthyl lactate, diazolidinyl urea, benzyl alcohol, methylparaben, BHT, propylparaben

*Refers to the ingredient hydrocortisone

†Contains 7 healing moisturizers and vitamins A, C & E

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Cortizone-10® Ointment

Active Ingredient:

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - insect bites
 - detergents
 - jewelry
 - cosmetics
 - soaps
 - seborrheic dermatitis
 - temporarily relieves external anal and genital itching
 - other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

- avoid contact with eyes
- · do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- · rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for itching of skin irritation, inflammation, and rashes:
 - adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
 - children under 2 years of age: ask a doctor

for external anal and genital itching, adults:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- · children under 12 years of age: ask a doctor

Other information

contents filled by weight, not volume

Inactive Ingredients

petrolatum

*Refers to the ingredient hydrocortisone

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www.chattem.com

0040437-02

Cortizone-10® Plus Creme

Active Ingredient:

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - · insect bites
 - detergents
 - jewelry
 - cosmetics
 - soaps
 - seborrheic dermatitis
 - temporarily relieves external anal and genital itching
 - other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor.
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• for itching of skin irritation, inflammation, and rashes:

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

• for external anal and genital itching, adults:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- · children under 12 years of age: ask a doctor

Other information

contents filled by weight, not volume

Inactive Ingredients

aloe barbadensis leaf juice, aluminum sulfate, beeswax, calcium acetate, cetearyl alcohol, cetyl alcohol, cholecalciferol, dextrin, glycerin, isopropyl palmitate, maltodextrin, methylparaben, mineral oil, petrolatum, propylene glycol, propylparaben, retinyl palmitate, sodium cetearyl sulfate, sodium lauryl sulfate, tocopheryl acetate, water, zea mays (corn) oil

*Refers to the ingredient hydrocortisone

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www.chattem.com 0040435-02

Principal Display Panel

Cooling
gel formula
itch relief
Cools
Itch
Fast
relief
that

lasts

- Sunburn
- Poison Ivy
- Insect Bites

Inflammation and redness

Cools itch on Contact

MAXIMUM STRENGTH

Cortizone-10®

COOLING RELIEF GEL

Net wt 1oz (28g) 1% Hydrocortisone Anti-Itch Gel

Principal Display Panel

10 Nourishing Ingredients Itch relief Fast Itch Lasts

Hours

- Eczema
- Sunburn
- Dry, Itchy Skin

Inflammation & redness

Hydrates irritated, itchy skin

PLUS ULTRA MOISTURIZING

MAXIMUM STRENGTH

Cortizone-10®

Net wt 1oz (28g) 1% Hydrocortisone Anti-Itch CREME

Principal Display Panel

Fast

Itch

Relief

Lasts

10

Hours

24 HOURS

MOISTURIZING

Itch Relief

- Eczema
- Psoriasis
- Itchy Skin

Inflammation & redness

Extra creamy formula, gentle on skin

INTENSIVE HEALING FORMULA[†]

MAXIMUM STRENGTH

Cortizone-10®

Net wt 1oz (28g) 1% Hydrocortisone Anti-Itch Crème

Principal Display Panel

Fast

Itch

Relief

Last

10

Hours

Water

Resistant Formula

Itch Relief

- Psoriasis
- Poison Ivy
- Irritation & Rashes

Inflammation & redness

Locks in moisture

Anti - Itch Ointment

Helps Seal in Healing

DOCTORS

#1 ITCH MEDICINE*TM

RECOMMEND

THE ITCH MEDICINE DOCTORS RECOMMEND*

MAXIMUM STRENGTH

Cortizone-10®

Net wt 1oz (28g) 1% Hydrocortisone Anti-Itch OINTMENT

Principal Display Panel

Fast

Itch

Relief

Last

10

Hours

Calming Aloe Vera Itch Relief

- Psoriasis
- Poison Ivy
- Insect Bites

Inflammation & redness

Soothes itch, irritation & rashes

DOCTORS

#1 ITCH MEDICINE*TM

RECOMMEND

MAXIMUM STRENGTH

Cortizone-10® plus

Net wt 1oz (28g) 1% Hydrocortisone Anti-Itch CREME

CORTIZONE 10 COOLING RELIEF

hydrocortisone gel

Duad		Infaun	nation
Prou	ucl	mom	iation

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0036
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Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
GLYCERIN (UNII: PDC6A3C0OX)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
POLYSORBATE 60 (UNII: CAL22UVI4M)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
WATER (UNII: 059QF0KO0R)			
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)			
ALCOHOL (UNII: 3K9958V90M)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41167-0036-0	1 in 1 CARTON	10/01/2008		
1		28 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:41167-0036-1	1 in 1 CARTON	10/01/2008		
2		35 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	10/01/2008		

CORTIZONE 10

hydrocortisone cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0039		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
ALUMINUM SULFATE (UNII: 34S289N54E)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
CALCIUM ACETATE (UNII: Y882YXF34X)			
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)			
GLYCERIN (UNII: PDC6A3C0OX)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
METHYLPARABEN (UNII: A218C7H19T)			
MINERAL OIL (UNII: T5L8T28FGP)			
PETROLATUM (UNII: 4T6H12BN9U)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
WATER (UNII: 059QF0KOOR)			

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41167-0039-1	1 in 1 CARTON	09/01/2007		
1		28 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:41167-0039-6	1 in 1 CARTON	09/01/2007		
2		56 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:41167-0039-0	1 in 1 CARTON	09/01/2007		
3		14 g in 1 TUBE; Type 0: Not a Combination Product			
4	NDC:41167-0039-9	1 in 1 CARTON	09/01/2007		
4		35 g in 1 TUBE; Type 0: Not a Combination Product			
5	NDC:41167-0039-2	2 in 1 CASE	07/01/2023		
5		56 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	09/01/2007		

CORTIZONE 10 INTENSIVE HEALING

hydrocortisone cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0035		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KOOR)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIMETHICONE (UNII: 92RU3N3Y10)		
PETROLATUM (UNII: 4T6H12BN9U)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
EDETIC ACID (UNII: 9G34HU7RV0)		
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
BENZYL ALCOHOL (UNII: LKG8494WBH)		
METHYLPARABEN (UNII: A218C7H19T)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
PROPYLPARABEN (UNII: Z8IX2SC10H)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41167-0035-0	1 in 1 CARTON	12/01/2007		
1		28 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:41167-0035-3	1 in 1 CARTON	12/01/2007		
2		56 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:41167-0035-2	1 in 1 CARTON	12/01/2007		
3		35 g in 1 TUBE; Type 0: Not a Combination Product			
4	NDC:41167-0035-1	2 in 1 CARTON	01/01/2023		
4		56 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/01/2007	

CORTIZONE 10

hydrocortisone ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0339	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g	

Inactive Ingredients Ingredient Name

PETROLATUM (UNII: 4T6H12BN9U)

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41167-0339-3	1 in 1 CARTON	09/01/2007		
1		28 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:41167-0339-6	1 in 1 CARTON	09/01/2007		
2		56 g in 1 TUBE; Type 0: Not a Combination Product			

Strength

Marketing Information				
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date				
OTC Monograph Drug	M017	09/01/2007		

CORTIZONE 10 PLUS

hydrocortisone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0105	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HYDROCORTISONE (UNII: WI4X0X7BPI) (HYDROCORTISONE - UNII:WI4X0X7BPI)	HYDROCORTISONE	10 ma in 1 a	

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM SULFATE (UNII: 34S289N54E)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLPARABEN (UNII: A218C7H19T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC10H)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
CORN OIL (UNII: 8470G57WFM)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0105-6	1 in 1 CARTON	09/01/2007	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:41167-0105-8	1 in 1 CARTON	09/01/2007	
2		35 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:41167-0105-7	1 in 1 CARTON	09/01/2007	
3		56 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/01/2007	

Labeler - Chattem, Inc. (003336013)

Revised: 2/2024 Chattem, Inc.