

DR. TALBOTS ORAL COMFORT PACK- pain fever relief and soothing gel
Talbot's Pharmaceuticals Family Products, LLC.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Active Ingredients

Calendula officinalis 12X HPUS

Chamomilla 12X HPUS

Echinacea angustifolia 12X HPUS

Eupatorium perfoliatum 12X HPUS

Hepar sulphuris calcareum 12X HPUS

Sulphur 12X HPUS

Cell Salts

Ferrum phosphoricum 12X HPUS

Kali muriaticum 6X HPUS

Purpose

Reduces inflammation

Hypersensitivity, irritability

Weakness, aching body

Aching pain, flu-like symptoms

Hypersensitive to cold, chills

Headache, symptoms of fever

Symptoms of fever

Glandular swellings, inflammation

Temporarily relieves

- irritability
- cold chills
- flu-like symptoms
- fever
- body ache
- general soreness
- swollen glands

Stop use and ask doctor if:

fever worsens or lasts more than 2 days

pain gets worse or lasts more than 7 days

other symptoms persist for more than 7 days or worsen

Ask a doctor before use if you are taking a prescription drug or have a serious medical condition.

Please consult your physician immediately for a worsening condition.

If pregnant or breastfeeding, consult your doctor before use.

Keep out of reach of children. In case of overdose (or accidental ingestion), get medical help or contact a Poison Control Center right away.

Shake before use, natural juice may settle

Measure only with the dosing syringe provided

Do not use dosing syringe with other products

On dosing syringe, weight is specific to product

On dosing syringe, ml = milliliter, lbs = pounds, kgs = kilograms

Children under 6 months of age, consult a medical professional before using this product.

For sudden onset of symptoms: Use every 15 minutes for up to 8 doses until symptoms relieved, then every 2 hours thereafter.

Children 6 - 18 lbs or 3 - 8 kgs

1.25 ml every 2 hours, reduce frequency when symptoms improve

Children 19 - 29 lbs or 9 - 13 kgs

2.5 ml every 2 hours, reduce frequency when symptoms improve

Children 30 - 90 lbs or 14 - 41 kgs

5 ml every 2 hours, reduce frequency when symptoms improve

Inactive ingredients

Citric acid, glycerin, grape juice, potassium sorbate, purified water

Questions or Comments?

Call us at 1-855-366-7755 (U.S.A. only) M-F 8am-5pm CST

Active ingredients

Arnica Montana, radix 30X HPUS 3.33%

Calcarea Phosphorica 12X HPUS 3.33%

Chamomilla 12X HPUS 3.33%

The letters "HPUS" indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Purposes†

sore gums

sensitive gums

pain associated with irritability

Keep this and all medications out of the reach of children. In case of accidental overdose

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70797-307-01	1 in 1 PACKAGE, COMBINATION; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	07/06/2020	
Quantity of Parts				
Part #	Package Quantity		Total Product Quantity	
Part 1	0 TUBE		2 g	
Part 2	0 BOTTLE		2 mL in 2	
Part 1 of 2				
NUBY SOOTHING GEL				
soothing gel gel				
Product Information				
Item Code (Source)		NDC:70797-240		
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ARNICA MONTANA ROOT (UNII: MUE8Y11327) (ARNICA MONTANA ROOT - UNII:MUE8Y11327)		ARNICA MONTANA ROOT	30 [hp_X] in 15 g	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28) (CALCIUM CATION - UNII:2M83C4R6ZB)		CALCIUM CATION	12 [hp_X] in 15 g	
MATRICARIA RECUTITA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)		MATRICARIA RECUTITA	12 [hp_X] in 15 g	
Inactive Ingredients				
Ingredient Name			Strength	
WATER (UNII: 059QF0KO0R)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SORBIC ACID (UNII: X045WJ989B)				
XANTHAN GUM (UNII: TTV12P4NEE)				
GLYCERIN (UNII: PDC6A3C0OX)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70797-240-15	15 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/06/2020	

Part 2 of 2

DR. TALBOTS PAIN FEVER RELIEF

calendula officinalis, chamomilla, echinacea angustifolia, eupatorium perfoliatum, hepar sulphuris calcareum, sulphur, ferrum phosphoricum, kali muriaticum liquid

Product Information

Item Code (Source)	NDC:70797-315
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUPATORIUM PERFOLIATUM FLOWERING TOP (UNII: 1W0775VX6E) (EUPATORIUM PERFOLIATUM FLOWERING TOP - UNII:1W0775VX6E)	EUPATORIUM PERFOLIATUM FLOWERING TOP	12 [hp_X] in 118 mL
FERROSFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROSFERRIC PHOSPHATE	12 [hp_X] in 118 mL
CALCIUM SULFIDE (UNII: 1MBW07J51Q) (CALCIUM SULFIDE - UNII:1MBW07J51Q)	CALCIUM SULFIDE	12 [hp_X] in 118 mL
ECHINACEA ANGUSTIFOLIA (UNII: VB06AV5US8) (ECHINACEA ANGUSTIFOLIA - UNII:VB06AV5US8)	ECHINACEA ANGUSTIFOLIA	12 [hp_X] in 118 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	12 [hp_X] in 118 mL
MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ) (MATRICARIA RECUTITA - UNII:G0R4UBI2ZZ)	MATRICARIA CHAMOMILLA	12 [hp_X] in 118 mL
COSMOS SULPHUREUS FLOWERING TOP (UNII: WKB165X336) (COSMOS SULPHUREUS FLOWERING TOP - UNII:WKB165X336)	COSMOS SULPHUREUS FLOWERING TOP	12 [hp_X] in 118 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CHLORIDE	6 [hp_X] in 118 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
WATER (UNII: 059QF0KO0R)	
CONCORD GRAPE JUICE (UNII: F7039Q79LP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70797-315-01	1 in 1 BOTTLE		
1	NDC:70797-315-04	118 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

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unapproved homeopathic		07/06/2020	

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Labeler - Talbot's Pharmaceuticals Family Products, LLC. (078855555)

Revised: 10/2021

Talbot's Pharmaceuticals Family Products, LLC.