

NORMAL SALT- sodium chloride tablet
GRAXCELL PHARMACEUTICAL, LLC

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.

Sodium Chloride Tablets, USP; Normal Salt Tablets (1 gram), 70795-1120

Active ingredient (in each tablet)

Sodium Chloride, USP 1.0 gram

Purpose

Electrolyte Replenisher

Uses

- for the preparation of normal isotonic solution of Sodium chloride
- as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration
- any alternative use as directed by a physician

Warnings

Enter section text here

Do not use

without consulting a physician

Ask a physician before use

if you have a sodium restricted diet due to multiple organ diseases

Stop use and ask a physician

If symptoms of heat cramps continue for more than 24 hours

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away

Directions



- to make isotonic solution of sodium chloride, dissolve one tablet in 120 ml (four ounces) of distilled water and use as directed by a physician
- if used as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration take one tablet orally as directed by your physician



Other information

- each tablet contains: sodium 394 mg
- store at room temperature 15°-30°C (59°-86°F)
- product does not contain any inactive ingredients

INACTIVE INGREDIENTS

NONE

 <p>NDC 70795-1120-1</p> <p>GRAXCELL PHARMACEUTICAL, LLC.</p> <p>Sodium Chloride Tablets, USP</p> <p>Normal Salt Tablets</p> <p>For solution or oral use</p> <p>100 1 gm Tablets</p>	<p>Drug Facts</p> <p>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.</p> <p>Active ingredient (in each tablet)</p> <p>Sodium Chloride, USP 1.0 gramElectrolyte Replenisher</p> <p>Purpose</p> <p>Electrolyte Replenisher</p> <p>Uses</p> <ul style="list-style-type: none"> ■ for the preparation of normal isotonic solution of Sodium chloride ■ as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration ■ any alternative use as directed by a physician <p>Warnings</p> <p>Do not use without consulting a physician</p> <p>Ask a physician before use if you have a sodium restricted diet due to multiple organ diseases</p> <p>Stop use and ask a physician if symptoms of heat cramps continue for more than 24 hours</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away</p> <p>Directions</p> <ul style="list-style-type: none"> ■ to make isotonic solution of sodium chloride, dissolve one tablet in 120 ml (four ounces) of distilled water and use as directed by a physician 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ if used as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration take one tablet orally as directed by your physician <p>Other information</p> <ul style="list-style-type: none"> ■ each tablet contains: sodium 394 mg ■ store at room temperature 15°-30°C (59°-86°F) ■ product does not contain any inactive ingredients <p>Manufactured by: GRAXCELL Pharmaceutical LLC 136 OAK Drive Syosset, N.Y. 11791</p> <p>Distributed by: GRAXCELL Pharmaceutical LLC 130 Knickerbocker Ave Bohemia, NY 11716 MADE IN USA</p>  <p>8 67017 00040 5</p>
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 <p>NDC 70795-1120-0</p> <p>GRAXCELL PHARMACEUTICAL, LLC.</p> <p>Sodium Chloride Tablets, USP</p> <p>Normal Salt Tablets</p> <p>For solution or oral use</p> <p>1000 1 gm Tablets</p>	<p>Drug Facts</p> <p>TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.</p> <p>Active ingredient (in each tablet)</p> <p>Sodium Chloride, USP 1.0 gramElectrolyte Replenisher</p> <p>Purpose</p> <p>Electrolyte Replenisher</p> <p>Uses</p> <ul style="list-style-type: none"> ■ for the preparation of normal isotonic solution of Sodium chloride ■ as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration ■ any alternative use as directed by a physician <p>Warnings</p> <p>Do not use without consulting a physician</p> <p>Ask a physician before use if you have a sodium restricted diet due to multiple organ diseases</p> <p>Stop use and ask a physician if symptoms of heat cramps continue for more than 24 hours</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away</p> <p>Directions</p> <ul style="list-style-type: none"> ■ to make isotonic solution of sodium chloride, dissolve one tablet in 120 ml (four ounces) of distilled water and use as directed by a physician ■ if used as an electrolyte replenisher for the prevention of heat cramps due to excessive perspiration take one tablet orally as directed by your physician <p>Other information</p> <ul style="list-style-type: none"> ■ each tablet contains: sodium 394 mg ■ store at room temperature 15°-30°C (59°-86°F) ■ product does not contain any inactive ingredients <p>Questions or comments? Call toll free 1-888-266-8818</p>	<p>Manufactured by: GRAXCELL Pharmaceutical LLC 136 OAK Drive Syosset, N.Y. 11791</p> <p>Distributed by: GRAXCELL Pharmaceutical LLC 130 Knickerbocker Ave Bohemia, NY 11716 MADE IN USA</p>  <p>8 63298 00027 1</p>
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NDC 70795-1120-3
GRAXCELL
 PHARMACEUTICAL, LLC.

Sodium Chloride Tablets, USP

NORMAL SALT TABLETS
 For solution or oral use

Value Size

1 Gram (15.4 gr.)

300 TABLETS

Drug Facts

Active ingredient (in each tablet) Sodium Chloride, USP 1.0 Gram **Purpose** Electrolyte Replenisher

Uses ■ for the preparation of normal isotonic solution of Sodium chloride
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Other information
 ■ each tablet contains: sodium 394 mg
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 ■ product does not contain any inactive ingredients

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

Manufactured by:
 Graxcell Pharmaceutical, LLC.
 136 Oak Drive
 Syosset, NY 11791

Distributed by:
 Graxcell Pharmaceutical, LLC.
 130 Knickerbocker Ave, Suite J
 Bohemia, NY 11716

MADE IN USA
 P009 (REV:12 - 19)



8 67017 00045 0

Lot No.:

Exp. Date:

NORMAL SALT

sodium chloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70795-1120
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	1 g

Inactive Ingredients

Ingredient Name	Strength
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	G13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70795-1120-1	120 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
	NDC:70795-	1000 in 1 BOTTLE; Type 0: Not a Combination		

2	NDC: 70795-1120-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	10/02/2017	
3	NDC: 70795-1120-3	300 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2020	
4	NDC: 70795-1120-4	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	10/02/2017	

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Establishment

Name	Address	ID/FEI	Business Operations
GRAXCELL PHARMACEUTICAL, LLC		056556923	manufacture(70795-1120)

Revised: 12/2021

GRAXCELL PHARMACEUTICAL, LLC