of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on
x.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage,
y, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document
actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from
x for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and
r forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized
ared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $1,000, e.g.
lry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed
n strict time limits, see current FedEx Service Guide.

OPEN IMMEDIATELY

URGENT RECALL INFORMATION

ATTN: FEDEX CSR
If Undeliverable DESTROY, do not return to shipper

printing this label:
ISIGNEE COPY - PLEASE PLACE IN FRONT OF POUCH
old the printed page along the horizontal line.
ace label in shipping pouch and affix it to your shipment.

ORIGIN ID:INTA (800) 868-5377
RECALL DEPARTMENT
INMAR
ONE WEST FOURTH STREET
SUITE 500
WINSTON SALEM, NC 27101
UNITED STATES US

SHIP DATE: 30MAY24
ACTWGT: 0.20 LB MAN
CAD: 0668701/CAFE3755

BILL THIRD PARTY

TO **RISK//RECALL MANAGER**
INDEPENDENT PHARMACY DISTRIBUTORS
INDEPENDENT PHARMACY DISTRIBUTORS L

HIGH POINT NC 27260
(800) 868-5377
INV: 410-1817
REF: RCL159-24

585C4/C458/AED7

FedEx Express

J233823851281uv

TRK# 0201 **6536 9387 0150**

FRI - 31 MAY 5:00P
STANDARD OVERNIGHT
ASR

24 DUFA

27260
GSO
NC-US

URGENT: DRUG RECALL

Potassium chloride Extended Release Capsules (750 mg) 10 mEq K Container Pack (Bottle pack container 100's and 500's) NDC for 750 mg US # 100's (68462-357-01), 500's (68462-357-05)

May 29, 2024

Dear Customer,

This is to inform you of a voluntary recall to Retail level involving the following drug product:
Potassium chloride Extended Release Capsules 750 mg

Sr. No	NDC	Batch No.	Expiry Date
1	68462-357-01	17221446	May-24
2	68462-357-01	17221445	May-24
3	68462-357-01	17221393	Jun-24
4	68462-357-01	17221403	Jun-24
5	68462-357-01	17221405	Jun-24
6	68462-357-01	17221503	Jun-24
7	68462-357-01	17221508	Jun-24
8	68462-357-01	17221567	Jul-24
9	68462-357-01	17221566	Jul-24
10	68462-357-01	17221719	Jul-24
11	68462-357-01	17221731	Jul-24
12	68462-357-01	17221891	Aug-24
13	68462-357-01	17221892	Aug-24
14	68462-357-01	17221900	Aug-24
15	68462-357-01	17221992	Aug-24
16	68462-357-01	17222022	Aug-24
17	68462-357-01	17222056	Sep-24
18	68462-357-01	17222043	Sep-24
19	68462-357-01	17222068	Sep-24
20	68462-357-01	17222079	Sep-24
21	68462-357-01	17222099	Sep-24
22	68462-357-01	17222103	Sep-24
23	68462-357-01	17222114	Sep-24
24	68462-357-01	17222119	Sep-24
25	68462-357-01	17222188	Sep-24

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Sr. No	NDC	Batch No.	Expiry Date
26	68462-357-01	17222199	Sep-24
27	68462-357-01	17222209	Sep-24
28	68462-357-01	17222200	Sep-24
29	68462-357-01	17222265	Oct-24
30	68462-357-01	17222269	Oct-24
31	68462-357-01	17222527	Nov-24
32	68462-357-01	17222530	Nov-24
33	68462-357-01	17222583	Nov-24
34	68462-357-01	17222586	Nov-24
35	68462-357-01	17230051	Nov-24
36	68462-357-01	17230075	Nov-24
37	68462-357-01	17230067	Nov-24
38	68462-357-05	17221197	May-24
39	68462-357-05	17221386	May-24
40	68462-357-05	17221385	May-24
41	68462-357-05	17221489	Jun-24
42	68462-357-05	17221504	Jun-24
43	68462-357-05	17221530	Jun-24
44	68462-357-05	17221561	Jul-24
45	68462-357-05	17221579	Jul-24
46	68462-357-05	17221568	Jul-24
47	68462-357-05	17221702	Jul-24
48	68462-357-05	17221704	Jul-24
49	68462-357-05	17221898	Aug-24
50	68462-357-05	17221993	Aug-24
51	68462-357-05	17222029	Aug-24
52	68462-357-05	17222300	Oct-24
53	68462-357-05	17222304	Oct-24
54	68462-357-05	17222278	Oct-24
55	68462-357-05	17222609	Oct-24
56	68462-357-05	17222395	Oct-24
57	68462-357-05	17222589	Nov-24
58	68462-357-05	17222605	Nov-24
59	68462-357-05	17222613	Nov-24

Recall of these batches has been initiated due to out of specification results observed in dissolution test (By AAS) during long term stability study (25 ± 2°C, 60 ± 5 % RH) at 18-Months' time point

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

interval, for the Potassium chloride Extended Release Capsules 750 mg 100's Container, batch number 17222043(Commercial batch).

Please see details of product batches listed in above table and refer enclosed product labels for ease in identifying the product.

Please examine your inventory and if you have any inventory available pertains to batch specified in above table then quarantine it immediately. Glenmark Pharmaceuticals, Inc. initiated shipment of this product on 06/15/2022.

In addition, if you are a wholesaler/ distributor, who have further distributed this product, please identify those customers and notify them at once of this Product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter. This recall should be carried out to the retail level.

We are requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Recall Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your recall return please contact Inmar at **877-883-9273**

Inmar office hours are Monday through Friday, from 9am to 5pm EST.

This recall is being made with the knowledge of the Food and Drug Administration.

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

Thomas Callaghan Digitally signed by Thomas Callaghan
Date: 2024.05.29 12:33:15 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

Product Labels

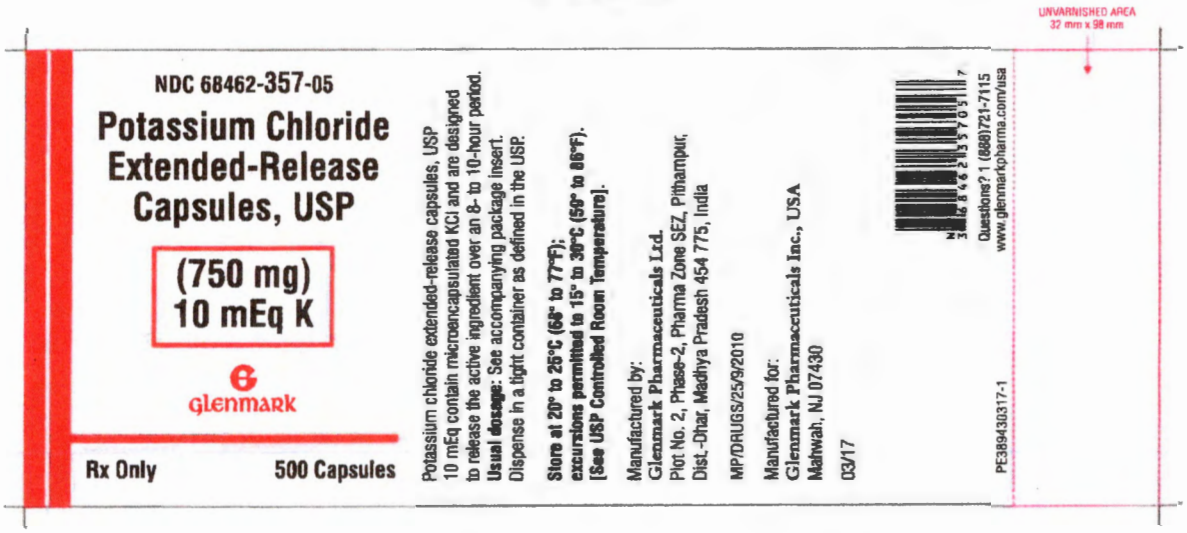
Recall Return Response Form

Glenmark Pharmaceuticals Inc., USA 750 Corporate Drive Mahwah, NJ 07430
Tel (201) 684-8000 Fax (201) 831-0080

Annual Reportable Change

Change in imprinting area as per the DSCSA requirements.

JAR SIZE : 1300 CC
SAME SIZE ARTWORK
500's count container label
(247 MM X 98 MM)



MINIMUM FONT SIZE: 9 pt

GLENMARK PHARMACEUTICALS LTD.		DATE:	PANTONE SHADE N): 186 C BLACK
PRODUCT NAME: POTASSIUM CHLORIDE ER CAPSULES 750 MG		PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE: PE38943 VERSION: 0317-1		RA	Regulatory Text
PHARMACODE:		QA:	Extra Text
COUNTRY: USA		PRODUCTION:	Machine Suitability
LOCATION: INDORE		REMARKS:	
PACK : 500 CAPSULES			
ACTUAL SIZE: 247 mm x 98 mm			
SPECIFICATION: A UV VARNISH COATED FASPRINT NG/PERMANENT (HITACY PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED			

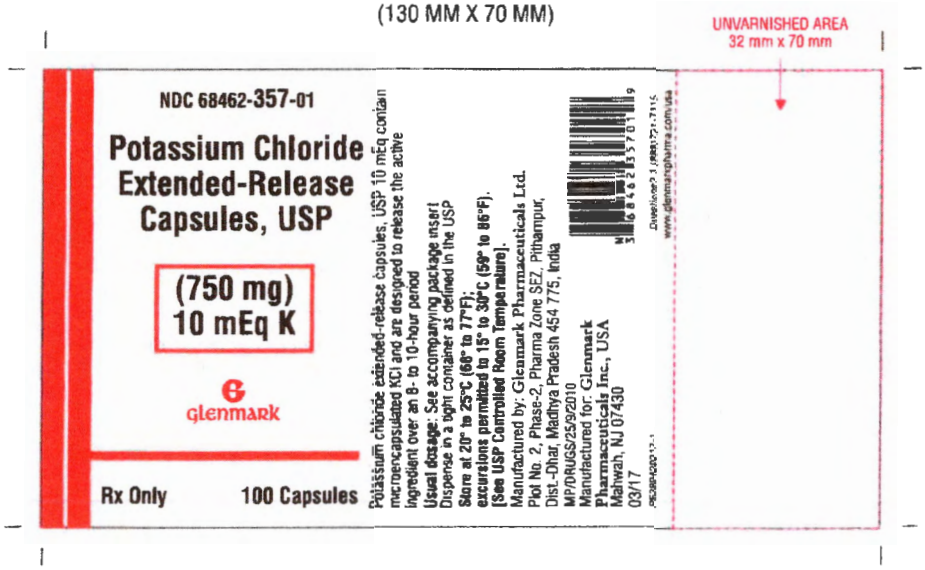
16JUN2017

Claudecapella Jun 16, 2017

Annual Reportable change

Change in Imprinting area as per the DSCSA requirements.

JAR SIZE : 300 CC
SAME SIZE ARTWORK
100's count container label
(130 MM X 70 MM)



MINIMUM FONT SIZE: 5 pt

GLENMARK PHARMACEUTICALS LTD		DATE:	PANTONE SHADE NO: 186 C BLACK
PRODUCT NAME:	POTASSIUM CHLORIDE ER CAPSULES 750 MG	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout
ITEM CODE:	PE38942 VERSION: 0317-1	RA	Regulatory Text
PHARMACODE:		QA:	Entire Text
COUNTRY:	USA	PRODUCTION:	Machine Suitability
LOCATION:	INDORE		
PACK :	100 CAPSULES	REMARKS:	
ACTUAL SIZE:	130 mm x 70 mm		
SPECIFICATION:	A UV VARNISH COATED FASPRINT NG/PERMANENT (HITAC)/ PET 23 STICKER LABEL FROM AVERY DENISON PRINTED AS PER APPROVED ARTWORK. BATCH PRINTING AREA REMAINS UNVARNISHED		

16JUN2017

Carole Capella Jun 16, 2017

One Glenmark label revision project

POTASSIUM CHLORIDE EXTENDED-RELEASE CAPSULES, USP, 10 mEq

Rx Only

DESCRIPTION:
Potassium chloride extended-release capsules, USP, 10 mEq is an oral dosage form of microencapsulated potassium chloride containing 750 mg of potassium chloride USP equivalent to 10 mEq of potassium.

Dispersibility of potassium chloride (KCl) is accomplished by microencapsulation and a dispersing agent. The resultant flow characteristics of the KCl microcapsules and the controlled release of K^+ ions by the microcapsular membrane are intended to avoid the possibility that excessive amounts of KCl can be localized at any point on the mucosa of the gastrointestinal tract.

Each crystal of KCl is microencapsulated by a process with an insoluble polymeric coating which functions as a semi-permeable membrane; it allows for the controlled release of potassium and chloride ions over an eight-to-ten-hour period. Fluids pass through the membrane and gradually dissolve the potassium chloride within the micro-capsules. The resulting potassium chloride solution slowly diffuses outward through the membrane. Potassium chloride extended-release capsules, USP, 10 mEq are electrolyte replenishers. The chemical name of the active ingredient is potassium chloride USP and the structural formula is KCl. Potassium chloride USP occurs as a granular crystalline powder. It is freely soluble in water and practically insoluble in ethanol.

The inactive ingredients are, ethylcellulose, FD&C red #3, FD&C yellow #6, gelatin, magnesium stearate, sodium lauryl sulfate, talc and titanium dioxide.

The imprinting ink contains the following: black iron oxide, potassium hydroxide and shellac.

CLINICAL PHARMACOLOGY:
Potassium ion is the principal intracellular cation of most body tissues. Potassium ions participate in a number of essential physiological processes, including the maintenance of intracellular tonicity, the transmission of nerve impulses, the contraction of cardiac, skeletal, and smooth muscle, and the maintenance of normal renal function.

The intracellular concentration of potassium is approximately 150 to 160 mEq per liter. The normal adult plasma concentration is 3.5 to 5 mEq per liter. An active ion transport system maintains this gradient across the plasma membrane.

Potassium is a normal dietary constituent and under steady-state conditions the amount of potassium absorbed from the gastrointestinal tract is equal to the amount excreted in the urine. The usual dietary intake of potassium is 50 to 100 mEq per day.

Potassium depletion will occur whenever the rate of potassium loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. Such depletion usually develops slowly as a consequence of therapy with diuretics, primary or secondary hyperaldosteronisms, diabetic ketoacidosis, or inadequate replacement of potassium in patients on prolonged parenteral nutrition.

Depletion can develop rapidly with severe diarrhea, especially if associated with vomiting. Potassium depletion due to these causes is usually accompanied by a concomitant loss of chloride and is manifested by hypokalemia and metabolic alkalosis. Potassium depletion may produce weakness, fatigue, disturbances of cardiac rhythm (primarily ectopic beats), prominent U-waves in the electrocardiogram, and in advanced cases, flaccid paralysis and/or impaired ability to concentrate urine.

If potassium depletion associated with metabolic alkalosis cannot be managed by correcting the fundamental cause of the deficiency, e.g., where the patient requires long-term diuretic therapy, supplemental potassium in the form of high potassium food or potassium chloride may be able to restore normal potassium levels.

In rare circumstances (e.g., patients with renal tubular acidosis) potassium depletion may be associated with metabolic acidosis and hyperchloremia. In such patients potassium replacement should be accomplished with potassium salts other than the chloride, such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

INDICATIONS AND USAGE:
BECAUSE OF REPORTS OF INTESTINAL AND GASTRIC ULCERATION AND BLEEDING WITH CONTROLLED-RELEASE POTASSIUM CHLORIDE PREPARATIONS, THESE DRUGS SHOULD BE RESERVED FOR THOSE PATIENTS WHO CANNOT TOLERATE OR REFUSE TO TAKE LIQUID OR EFFERVESCENT POTASSIUM PREPARATIONS OR FOR PATIENTS IN WHOM THERE IS A PROBLEM OF COMPLIANCE WITH THESE PREPARATIONS.

1. For the treatment of patients with hypokalemia with or without metabolic alkalosis, in digitalis intoxications, and in patients with hypokalemic familial periodic paralysis. If hypokalemia is the result of diuretic therapy, consideration should be given to the use of a lower dose of diuretic, which may be sufficient without leading to hypokalemia.
2. For the prevention of hypokalemia in patients who would be at particular risk if hypokalemia were to develop e.g., digitalized patients or patients with significant cardiac arrhythmias, hepatic cirrhosis with ascites, states of aldosterone excess with normal renal function, potassium-losing nephropathy, and certain diarrheal states.

The use of potassium salts in patients receiving diuretics for uncomplicated essential hypertension is often unnecessary when such patients have a normal dietary pattern and when low doses of the diuretic are used. Serum potassium should be checked periodically, however, and if hypokalemia occurs, dietary supplementation with potassium-containing foods may be adequate to control milder cases, in more severe cases, and if dose adjustment of the diuretic is ineffective or unwarranted, supplementation with potassium salts may be indicated.

CONTRAINDICATIONS:
Potassium supplements are contraindicated in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate any of the following conditions: chronic renal failure, systemic acidosis such as diabetic acidosis, acute dehydration, extensive tissue breakdown as in severe burns, adrenal insufficiency, or the administration of a potassium-sparing diuretic (e.g., spironolactone, triamterene, amiloride) (see **OVERDOSAGE**).

Controlled-release formulations of potassium chloride have produced esophageal ulceration in certain cardiac patients with esophageal compression due to an enlarged left atrium. Potassium supplementation, when indicated in such patients, should be given as a liquid preparation.

All solid oral dosage forms of potassium chloride are contraindicated in any patient in whom there is structural, pathological (e.g., diabetic gastroparesis) or pharmacologic (use of anticholinergic agents or other agents with anticholinergic properties at sufficient doses to exert anticholinergic effects) cause for arrest or delay in capsule passage through the gastrointestinal tract.

WARNINGS:

Hyperkalemia (see OVERDOSAGE)
In patients with impaired mechanisms for excreting potassium, the administration of potassium salts can produce hyperkalemia and cardiac arrest. This occurs most commonly in patients given potassium by the intravenous route but may also occur in patients given potassium orally. Potentially fatal hyperkalemia can develop rapidly and be asymptomatic. The use of potassium salts in patients with chronic renal disease, or any other condition which impairs potassium excretion, requires particularly careful monitoring of the serum potassium concentration and appropriate dosage adjustments.

Interaction with Potassium-Sparing Diuretics
Hypokalemia should not be treated by the concomitant administration of potassium salts and a potassium-sparing diuretic (e.g., spironolactone, triamterene, or amiloride), since the simultaneous administration of these agents can produce severe hyperkalemia.

Interaction with Angiotensin Converting Enzyme Inhibitors
Angiotensin converting enzyme (ACE) inhibitors (e.g., captopril, enalapril) will produce some potassium retention by inhibiting aldosterone production. Potassium supplements should be given to patients receiving ACE inhibitors only with close monitoring.

Gastrointestinal Lesions
Solid oral dosage forms of potassium chloride can produce ulcerative and/or stenotic lesions of the gastrointestinal tract. Based on spontaneous adverse reaction reports, enteric coated preparations of potassium chloride are associated with an increased frequency of small bowel lesions (40 to 50 per 100,000 patient years) compared to sustained-release wax matrix formulations (less than one per 100,000 patient years). Because of the lack of extensive marketing experience with microencapsulated products, a comparison between such products and wax matrix or enteric coated products is not available. Potassium chloride extended-release capsules, USP, 10 mEq are microencapsulated capsules formulated to provide a controlled rate of release of microencapsulated potassium chloride and thus to minimize the possibility of high local concentration of potassium near the gastrointestinal wall.

Prospective trials have been conducted in normal human volunteers in which the upper gastrointestinal tract was evaluated by endoscopic inspection before and after one week of solid oral potassium chloride therapy. The ability of this model to predict events occurring in usual clinical practice is unknown. Trials which approximated usual clinical practice did not reveal any clear differences between the wax matrix and microencapsulated dosage forms. In contrast, there was a higher incidence of gastric and duodenal lesions in subjects receiving a high dose of a wax matrix controlled-release formulation under conditions which did not resemble usual or recommended clinical practice (i.e., 96 mEq per day in divided doses of potassium chloride administered to fasted patients, in the presence of an anticholinergic drug to delay gastric emptying). The upper gastrointestinal lesions observed by endoscopy were asymptomatic and were not accompanied by evidence of bleeding (hemoccult testing). The relevance of these findings to the usual conditions (i.e., non-fasting, no anticholinergic agent, smaller doses) under which controlled-release potassium chloride products are used is uncertain; epidemiologic studies have not identified an elevated risk, compared to microencapsulated products, for upper gastrointestinal lesions in patients receiving wax matrix formulations. Potassium chloride extended-release capsules, USP, 10 mEq should be discontinued immediately and the possibility of ulceration, obstruction or perforation considered if severe vomiting, abdominal pain, distention, or gastrointestinal bleeding occur.

Metabolic Acidosis
Hypokalemia in patients with metabolic acidosis should be treated with an alkalinizing potassium salt such as potassium bicarbonate, potassium citrate, potassium acetate, or potassium gluconate.

PRECAUTIONS:

General
The diagnosis of potassium depletion is ordinarily made by demonstrating hypokalemia in a patient with a clinical history suggesting some cause for potassium depletion. In interpreting the serum potassium level, the physician should bear in mind that acute alkalosis per se can produce hypokalemia in the absence of a deficit in total body potassium, while acute acidosis per se can increase the serum potassium concentration into the normal range even in the

Skeen Sonas Apr 02 2015 Claude Capella Apr 07, 2015

GLENMARK GENERICS LTD.	**DATE:** 02.03.2015	**PANTONE SHADE NO:** 1 (Black)	
PRODUCT NAME: Potassium Chloride ER Cap USP 10 mEq(tns-Fr)	**PKG. DEV.:**	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE32422 **VERSION:** 0315-1	**RA**	Regulatory Text	
PHARMACODE:	**QA:**	Entire Text	
COUNTRY: US	**PRODUCTION:**	Machine Suitability	
LOCATION: Goa	**REMARKS:**		
PACK : 240 x 171 mm			
ACTUAL SIZE: 31 x 29 mm			
SPECIFICATION: 40 gsm Bible Paper			

Temple Packaging Pvt. Ltd. Font: 6 pt helvetica condensed Sap code: 40100005598 File: 38412 V:1 Shaji

One Glenmark label revision project

presence of a reduced total body potassium The treatment of potassium depletion, particularly in the presence of cardiac disease, renal disease, or acidosis, requires careful attention to acid-base balance and appropriate monitoring of serum electrolytes, the electrocardiogram, and the clinical status of the patient

Information For Patients
Physicians should consider reminding the patient of the following: To take each dose with meals and with a full glass of water or other suitable liquid. To take each dose without crushing, chewing, or sucking the capsules. To take this medicine following the frequency and amount prescribed by the physician. This is especially important if the patient is also taking diuretics and/or digitalis preparations.

To check with the physician if there is trouble swallowing capsules or if the capsules seem to stick in the throat

To check with the physician at once if tarry stools or other evidence of gastrointestinal bleeding is noticed

Laboratory Tests
Regular serum potassium determinations are recommended, especially in patients with renal insufficiency or diabetic nephropathy. When blood is drawn for analysis of plasma potassium it is important to recognize that artifactual elevations can occur after improper venipuncture technique or as a result of in vitro hemolysis of the sample

Drug Interactions
Potassium-sparing diuretics, angiotensin converting enzyme inhibitors (see **WARNINGS**)

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity, mutagenicity and fertility studies in animals have not been performed Potassium is a normal dietary constituent

Pregnancy: Teratogenic Effects: Category C
Animal reproduction studies have not been conducted with potassium chloride extended-release capsules, USP, 10 mEq. It is unlikely that potassium supplementation that does not lead to hyperkalemia would have an adverse effect on the fetus or would affect reproductive capacity

Nursing Mothers
The normal potassium ion content of human milk is about 13 mEq per liter Since oral potassium becomes part of the body potassium pool, so long as body potassium is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk

Pediatric Use
Safety and effectiveness in pediatric patients have not been established

Geriatric Use
Clinical studies of potassium chloride extended-release capsules did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function

ADVERSE REACTIONS:
One of the most severe adverse effects is hyperkalemia (see **CONTRAINDICATIONS, WARNINGS, AND OVERDOSAGE**)

Gastrointestinal bleeding and ulceration have been reported in patients treated with potassium chloride extended-release capsules, USP, 10 mEq (see **CONTRAINDICATIONS** and **WARNINGS**). In addition to gastrointestinal bleeding and ulceration, perforation and obstruction have been reported in patients treated with other solid KCl dosage forms, and may occur with potassium chloride extended-release capsules, USP, 10 mEq. The most common adverse reactions to the oral potassium salts are nausea, vomiting, flatulence, abdominal discomfort, and diarrhea These symptoms are due to irritation of the gastrointestinal tract and are best managed by taking the dose with meals, or reducing the amount taken at one time Skin rash has been reported rarely with potassium preparations

OVERDOSAGE:
The administration of oral potassium salts to persons with normal excretory mechanisms for potassium rarely causes serious hyperkalemia. However, if excretory mechanisms are impaired or if potassium is administered too rapidly intravenously, potentially fatal hyperkalemia can result (see **CONTRAINDICATIONS** and **WARNINGS**) It is important to recognize that hyperkalemia is usually asymptomatic and may be manifested only by an increased serum potassium concentration (6.5 to 8.0 mEq/L) and characteristic electrocardiographic changes (peaking of T-waves, loss of P-waves, depression of ST segment, and prolongation of the QT interval)

Late manifestations include muscle paralysis and cardiovascular collapse from cardiac arrest (9 to 12 mEq/L).

Treatment measures for hyperkalemia include the following: (1) elimination of foods and medications containing potassium and of any agents with potassium-sparing properties; (2) intravenous administration of 300 to 500 mL/hr of 10% dextrose solution containing 10 to 20 units of crystalline insulin per 1,000 mL; (3) correction of acidosis, if present, with intravenous sodium bicarbonate; (4) use of exchange resins, hemodialysis, or peritoneal dialysis. In treating hyperkalemia, it should be recalled that in patients who have been stabilized on digitalis, too rapid a lowering of the serum potassium concentration can produce digitalis toxicity The extended release feature means that absorption and toxic effects may be delayed for hours Consider standard measures to remove any unabsorbed drug

DOSAGE AND ADMINISTRATION:
The usual dietary intake of potassium by the average adult is 50 to 100 mEq per day Potassium depletion sufficient to cause hypokalemia usually requires the loss of 200 or more mEq of potassium from the total body store

Dosage must be adjusted to the individual needs of each patient The dose for the prevention of hypokalemia is typically in the range of 20 mEq per day. Doses of 40 to 100 mEq per day or more are used for the treatment of potassium depletion Dosage should be divided if more than 20 mEq per day is given such that no more than 20 mEq is given in a single dose Because of the potential for gastric irritation (see **WARNINGS**), potassium chloride extended-release capsules, USP, 10 mEq should be taken with meals and with a full glass of water or other liquid.

Patients who have difficulty swallowing capsules may sprinkle the contents of the capsule onto a spoonful of soft food. The soft food, such as applesauce or pudding, should be swallowed immediately without chewing and followed with a glass of cool water or juice to ensure complete swallowing of the microcapsules. The food used should not be hot and should be soft enough to be swallowed without chewing. Any microcapsule/food mixture should be used immediately and not stored for future use

HOW SUPPLIED:
Potassium chloride extended-release capsules, USP, 10 mEq are hard gelatin capsules with opaque white body with '357' imprinted in black and opaque orange cap with 'G' imprinted in black, each containing 750 mg microencapsulated potassium chloride (equivalent to 10 mEq K) in bottles of 100 (NDC 68462-357-01) and bottles of 500 (NDC 68462-357-05)

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]
Dispense in tight container

Manufactured by:
Glenmark Pharmaceuticals Ltd.
Plot No.2, Phase-2, Pharma Zone SEZ,
Pithampur, Dist -Dhar,
Madhya Pradesh 454 775, India

Manufactured for:
glenmark
Glenmark Pharmaceuticals Inc., USA
Mahwah, NJ 07430

Questions?
1 (888)721-7115
www.glenmarkpharma.com/usa

March 2015

APPROVED BY

Sheen Samson Apr 02, 2015
Carol Capella Apr 07, 2015

PE32422015-1

GLENMARK GENERICS LTD.	DATE: 02.03 2015	PANTONE SHADE NO: 1 (Black)	
PRODUCT NAME: Potassium Chloride ER Cap USP 10 mEq(Ins-Bk)	PKG. DEV.:	Item code, Version, Consistency of Design, overprint area, Pack size, Dimensions & Layout	
ITEM CODE: PE32422 VERSION: 0315-1	RA	Regulatory Text	
PHARMACODE:	QA:	Entire Text	
COUNTRY: US	PRODUCTION:	Machine Suitability	
LOCATION: Goa	REMARKS:		
PACK : 240 x 171 mm			
ACTUAL SIZE: 31 x 29 mm			
SPECIFICATION: 40 gsm Bible Paper			

Temple Packaging Pvt. Ltd. Font: 6 pt helvetica condensed Sap code: 40100005598 File: 38412 V:1 Sh:1

Glenmark
A new way for a new world

RECALL RETURN RESPONSE FORM

Potassium chloride Extended Release Capsules (750 mg) 10 mEq K 100's and 500's Container Pack
NDC # for 750 mg 100's (68462-357-01)
NDC # for 750 mg 500's (68462-357-05)
Retail Level
05/29/2024

Please fill out this form completely. By doing so, this will acknowledge that you have read and understood the recall instructions and have taken the appropriate action.

Customer Name:	DEA#:	
DEA # is required, if it is not provided, the processing of your form will be delayed.		
Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	
DEBIT MEMO# (If unsure, leave blank):		

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:	
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

☐ I confirm that all locations that received the impacted products have been notified to the retail level _____(Initial and date)

☐ I do not have any stock of the recalled items. **OR**

☐ I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels_____.

Sr. No	Item Description	NDC	Lot#/ Pack Size	Expiry Date	Total Full/Sealed and Partial/Open Bottle Count
1	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221446/100's pack container	May-24	

Sr. No	Item Description	NDC	Lot#/ Pack Size	Expiry Date	Total Full/Sealed and Partial/Open Bottle Count
2	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221445/100's pack container	May-24	
3	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221393/100's pack container	Jun-24	
4	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221403/100's pack container	Jun-24	
5	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221405/100's pack container	Jun-24	
6	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221503/100's pack container	Jun-24	
7	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221508/100's pack container	Jun-24	
8	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221567/100's pack container	Jul-24	
9	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221566/100's pack container	Jul-24	
10	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221719/100's pack container	Jul-24	
11	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221731/100's pack container	Jul-24	
12	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221891/100's pack container	Aug-24	
13	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221892/100's pack container	Aug-24	
14	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221900/100's pack container	Aug-24	
15	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17221992/100's pack container	Aug-24	
16	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222022/100's pack container	Aug-24	
17	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222056/100's pack container	Sep-24	
18	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222043/100's pack container	Sep-24	
19	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222068/100's pack container	Sep-24	
20	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222079/100's pack container	Sep-24	
21	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222099/100's pack container	Sep-24	
22	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222103/100's pack container	Sep-24	
23	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222114/100's pack container	Sep-24	

Sr. No	Item Description	NDC	Lot#/ Pack Size	Expiry Date	Total Full/Sealed and Partial/Open Bottle Count
24	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222119/100's pack container	Sep-24	
25	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222188/100's pack container	Sep-24	
26	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222199/100's pack container	Sep-24	
27	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222209/100's pack container	Sep-24	
28	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222200/100's pack container	Sep-24	
29	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222265/100's pack container	Oct-24	
30	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222269/100's pack container	Oct-24	
31	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222527/100's pack container	Nov-24	
32	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222530/100's pack container	Nov-24	
33	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222583/100's pack container	Nov-24	
34	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17222586/100's pack container	Nov-24	
35	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17230051/100's pack container	Nov-24	
36	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17230075/100's pack container	Nov-24	
37	POTASSIUM CL ER CAP 10MEQ 100	68462-357-01	17230067/100's pack container	Nov-24	
38	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221197/500's pack container	May-24	
39	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221386/500's pack container	May-24	
40	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221385/500's pack container	May-24	
41	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221489/500's pack container	Jun-24	
42	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221504/500's pack container	Jun-24	
43	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221530/500's pack container	Jun-24	
44	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221561/500's pack container	Jul-24	
45	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221579/500's pack container	Jul-24	

Glenmark
A new way for a new world

Sr. No	Item Description	NDC	Lot#/ Pack Size	Expiry Date	Total Full/Sealed and Partial/Open Bottle Count
46	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221568/500's pack container	Jul-24	
47	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221702/500's pack container	Jul-24	
48	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221704/500's pack container	Jul-24	
49	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221898/500's pack container	Aug-24	
50	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17221993/500's pack container	Aug-24	
51	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222029/500's pack container	Aug-24	
52	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222300/500's pack container	Oct-24	
53	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222304/500's pack container	Oct-24	
54	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222278/500's pack container	Oct-24	
55	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222609/500's pack container	Oct-24	
56	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222395/500's pack container	Oct-24	
57	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222589/500's pack container	Nov-24	
58	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222605/500's pack container	Nov-24	
59	POTASSIUM CL ER CAP 10MEQ 500	68462-357-05	17222613/500's pack container	Nov-24	

If you have any questions regarding this form or product return please contact Inmar at **877-883-9273** Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

Recall Event ID N131178 / RCL159-24