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INFORMATION FOR THE PHYSICIAN GLUCAGON FOR INJECTION (rDNA ORIGIN)

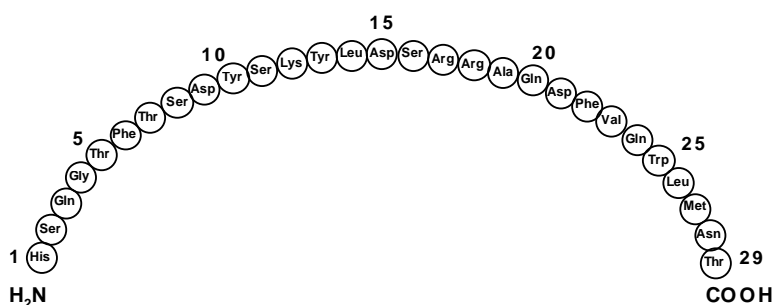
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DESCRIPTION

7 Glucagon for Injection (rDNA origin) is a polypeptide hormone identical to human glucagon
8 that increases blood glucose and relaxes smooth muscle of the gastrointestinal tract. Glucagon is
9 synthesized in a special non-pathogenic laboratory strain of *Escherichia coli* bacteria that has
10 been genetically altered by the addition of the gene for glucagon.

11 Glucagon is a single-chain polypeptide that contains 29 amino acid residues and has a
12 molecular weight of 3483.

13 The empirical formula is $C_{153}H_{225}N_{43}O_{49}S$. The primary sequence of glucagon is shown below.



14
15 Crystalline glucagon is a white to off-white powder. It is relatively insoluble in water but is
16 soluble at a pH of less than 3 or more than 9.5.

17 Glucagon is available for use intravenously, intramuscularly, or subcutaneously in a kit that
18 contains a vial of sterile glucagon and a syringe of sterile diluent. The vial contains 1 mg (1 unit)
19 of glucagon and 49 mg of lactose. Hydrochloric acid may have been added during manufacture to
20 adjust the pH of the glucagon. One International Unit of glucagon is equivalent to 1 mg of
21 glucagon.¹ The diluent syringe contains 12 mg/mL of glycerin, Water For Injection, and
22 hydrochloric acid.

23

CLINICAL PHARMACOLOGY

24 Glucagon increases blood glucose concentration and is used in the treatment of hypoglycemia.
25 Glucagon acts only on liver glycogen, converting it to glucose.

26 Glucagon administered through a parenteral route relaxes smooth muscle of the stomach,
27 duodenum, small bowel, and colon.

28

Pharmacokinetics

29 Glucagon has been studied following intramuscular, subcutaneous, and intravenous
30 administration in adult volunteers. Administration of the intravenous glucagon showed dose
31 proportionality of the pharmacokinetics between 0.25 and 2.0 mg. Calculations from a 1 mg dose
32 showed a small volume of distribution (mean, 0.25 L/kg) and a moderate clearance (mean,
33 13.5 mL/min/kg). The half-life was short, ranging from 8 to 18 minutes.

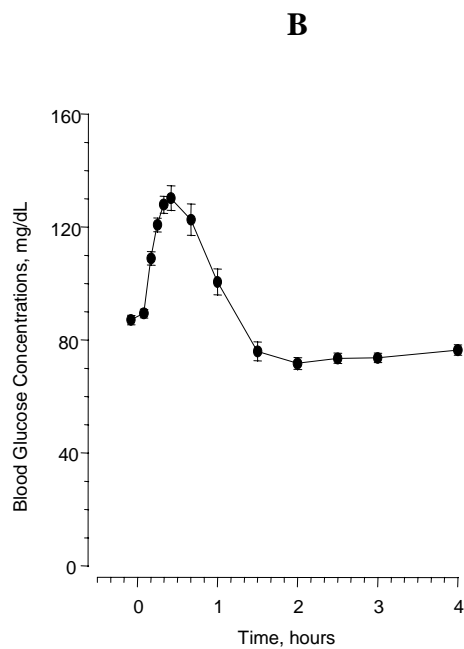
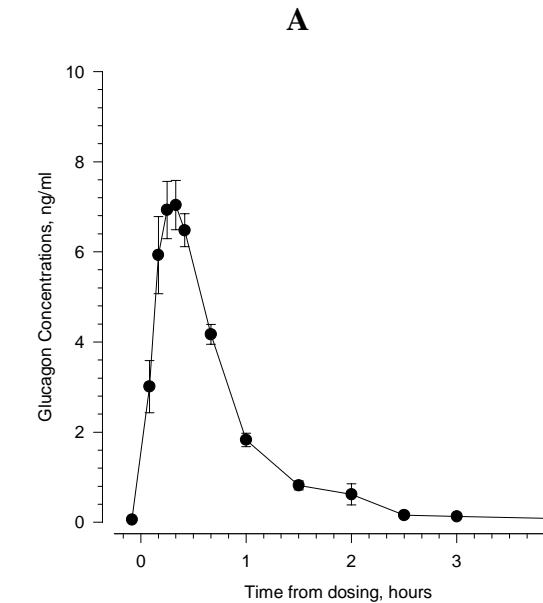
34 Maximum plasma concentrations of 7.9 ng/mL were achieved approximately 20 minutes after
35 subcutaneous administration (*see* Figure 1A). With intramuscular dosing, maximum plasma
36 concentrations of 6.9 ng/mL were attained approximately 13 minutes after dosing.

37 Glucagon is extensively degraded in liver, kidney, and plasma. Urinary excretion of intact
38 glucagon has not been measured.

39 **Pharmacodynamics**

40 In a study of 25 volunteers, a subcutaneous dose of 1 mg glucagon resulted in a mean peak
41 glucose concentration of 136 mg/dL 30 minutes after injection (*see* Figure 1B). Similarly,
42 following intramuscular injection, the mean peak glucose level was 138 mg/dL, which occurred
43 at 26 minutes after injection. No difference in maximum blood glucose concentration between
44 animal-sourced and rDNA glucagon was observed after subcutaneous and intramuscular
45 injection.

Figure 1
Mean (\pm SE) serum glucagon and blood glucose levels after subcutaneous injection of glucagon (1 mg) in 25 normal volunteers



46

47

INDICATIONS AND USAGE

48 *For the treatment of hypoglycemia:*

49 Glucagon is indicated as a treatment for severe hypoglycemia.

50 Because patients with type 1 diabetes may have less of an increase in blood glucose levels
 51 compared with a stable type 2 patient, supplementary carbohydrate should be given as soon as
 52 possible, especially to a pediatric patient.

53 *For use as a diagnostic aid:*

54 Glucagon is indicated as a diagnostic aid in the radiologic examination of the stomach,
55 duodenum, small bowel, and colon when diminished intestinal motility would be advantageous.

56 Glucagon is as effective for this examination as are the anticholinergic drugs. However, the
57 addition of the anticholinergic agent may result in increased side effects.

58 **CONTRAINDICATIONS**

59 Glucagon is contraindicated in patients with known hypersensitivity to it or in patients with
60 known pheochromocytoma.

61 **WARNINGS**

62 Glucagon should be administered cautiously to patients with a history suggestive of
63 insulinoma, pheochromocytoma, or both. In patients with insulinoma, intravenous administration
64 of glucagon may produce an initial increase in blood glucose; however, because of glucagon's
65 hyperglycemic effect the insulinoma may release insulin and cause subsequent hypoglycemia. A
66 patient developing symptoms of hypoglycemia after a dose of glucagon should be given glucose
67 orally, intravenously, or by gavage, whichever is most appropriate.

68 Exogenous glucagon also stimulates the release of catecholamines. In the presence of
69 pheochromocytoma, glucagon can cause the tumor to release catecholamines, which may result
70 in a sudden and marked increase in blood pressure. If a patient develops a sudden increase in
71 blood pressure, 5 to 10 mg of phentolamine mesylate may be administered intravenously in an
72 attempt to control the blood pressure.

73 Generalized allergic reactions, including urticaria, respiratory distress, and hypotension, have
74 been reported in patients who received glucagon by injection.

75 **PRECAUTIONS**

76 **General**

77 Glucagon is effective in treating hypoglycemia only if sufficient liver glycogen is present.
78 Because glucagon is of little or no help in states of starvation, adrenal insufficiency, or chronic
79 hypoglycemia, hypoglycemia in these conditions should be treated with glucose.

80 **Information for Patients**

81 Refer patients and family members to the attached Information for the User for instructions
82 describing the method of preparing and injecting glucagon. Advise the patient and family
83 members to become familiar with the technique of preparing glucagon before an emergency
84 arises. Instruct patients to use 1 mg (1 unit) for adults and 1/2 the adult dose (0.5 mg) [0.5 unit]
85 for pediatric patients weighing less than 44 lb (20 kg).

86 Patients and family members should be informed of the following measures to prevent
87 hypoglycemic reactions due to insulin:

- 88 1. Reasonable uniformity from day to day with regard to diet, insulin, and exercise.
- 89 2. Careful adjustment of the insulin program so that the type (or types) of insulin, dose, and
90 time (or times) of administration are suited to the individual patient.
- 91 3. Frequent testing of the blood or urine for glucose so that a change in insulin requirements
92 can be foreseen.
- 93 4. Routine carrying of sugar, candy, or other readily absorbable carbohydrate by the patient
94 so that it may be taken at the first warning of an oncoming reaction.

95 To prevent severe hypoglycemia, patients and family members should be informed of the
96 symptoms of mild hypoglycemia and how to treat it appropriately.

97 Family members should be informed to arouse the patient as quickly as possible because
98 prolonged hypoglycemia may result in damage to the central nervous system. Glucagon or

99 intravenous glucose should awaken the patient sufficiently so that oral carbohydrates may be
100 taken.

101 Patients should be advised to inform their physician when hypoglycemic reactions occur so that
102 the treatment regimen may be adjusted if necessary.

103 **Laboratory Tests**

104 Blood glucose determinations should be obtained to follow the patient with hypoglycemia until
105 patient is asymptomatic.

106 **Carcinogenesis, Mutagenesis, Impairment of Fertility**

107 Because glucagon is usually given in a single dose and has a very short half-life, no studies
108 have been done regarding carcinogenesis. In a series of studies examining effects on the bacterial
109 mutagenesis (Ames) assay, it was determined that *an increase* in colony counts was related to
110 technical difficulties in running this assay with peptides and was not due to mutagenic activities
111 of the glucagon.

112 Reproduction studies have been performed in rats at doses up to 2 mg/kg glucagon
113 administered two times a day (up to 40 times the human dose based on body surface area, mg/m²)
114 and have revealed no evidence of impaired fertility.

115 **Pregnancy**

116 *Pregnancy Category B* — Reproduction studies have not been performed with recombinant
117 glucagon. However, studies with animal-sourced glucagon were performed in rats at doses up to
118 2 mg/kg glucagon administered two times a day (up to 40 times the human dose based on body
119 surface area, mg/m²), and have revealed no evidence of impaired fertility or harm to the fetus due
120 to glucagon. There are, however, no adequate and well-controlled studies in pregnant women.
121 Because animal reproduction studies are not always predictive of human response, this drug
122 should be used during pregnancy only if clearly needed.

123 **Nursing Mothers**

124 It is not known whether this drug is excreted in human milk. Because many drugs are excreted
125 in human milk, caution should be exercised when glucagon is administered to a nursing woman.
126 If the drug is excreted in human milk during its short half-life, it will be hydrolyzed and absorbed
127 like any other polypeptide. Glucagon is not active when taken orally because it is destroyed in the
128 gastrointestinal tract before it can be absorbed.

129 **Pediatric Use**

130 For the treatment of hypoglycemia: The use of glucagon in pediatric patients has been reported
131 to be safe and effective.²⁻⁶

132 For use as a diagnostic aid: Effectiveness has not been established in pediatric patients.

133 **Geriatric Use**

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

140 **ADVERSE REACTIONS**

141 Severe adverse reactions are very rare, although nausea and vomiting may occur occasionally.
142 These reactions may also occur with hypoglycemia. Generalized allergic reactions have been
143 reported (*see* WARNINGS). In a three month controlled study of 75 volunteers comparing

144 animal-sourced glucagon with glucagon manufactured through rDNA technology, no
145 glucagon-specific antibodies were detected in either treatment group.

146 OVERDOSAGE

147 *Signs and Symptoms* — If overdosage occurs, nausea, vomiting, gastric hypotonicity, and
148 diarrhea would be expected without causing consequential toxicity.

149 Intravenous administration of glucagon has been shown to have positive inotropic and
150 chronotropic effects. A transient increase in both blood pressure and pulse rate may occur
151 following the administration of glucagon. Patients taking β -blockers might be expected to have a
152 greater increase in both pulse and blood pressure, an increase of which will be transient because
153 of glucagon's short half-life. The increase in blood pressure and pulse rate may require therapy in
154 patients with pheochromocytoma or coronary artery disease.

155 When glucagon was given in large doses to patients with cardiac disease, investigators reported
156 a positive inotropic effect. These investigators administered glucagon in doses of 0.5 to
157 16 mg/hour by continuous infusion for periods of 5 to 166 hours. Total doses ranged from 25 to
158 996 mg, and a 21-month-old infant received approximately 8.25 mg in 165 hours. Side effects
159 included nausea, vomiting, and decreasing serum potassium concentration. Serum potassium
160 concentration could be maintained within normal limits with supplemental potassium.

161 The intravenous median lethal dose for glucagon in mice and rats is approximately 300 mg/kg
162 and 38.6 mg/kg, respectively.

163 Because glucagon is a polypeptide, it would be rapidly destroyed in the gastrointestinal tract if
164 it were to be accidentally ingested.

165 *Treatment* — To obtain up-to-date information about the treatment of overdose, a good
166 resource is your certified Regional Poison Control Center. Telephone numbers of certified poison
167 control centers are listed in the *Physicians' Desk Reference (PDR)*. In managing overdosage,
168 consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug
169 kinetics in your patient.

170 In view of the extremely short half-life of glucagon and its prompt destruction and excretion,
171 the treatment of overdosage is symptomatic, primarily for nausea, vomiting, and possible
172 hypokalemia.

173 If the patient develops a dramatic increase in blood pressure, 5 to 10 mg of phentolamine
174 mesylate has been shown to be effective in lowering blood pressure for the short time that control
175 would be needed.

176 Forced diuresis, peritoneal dialysis, hemodialysis, or charcoal hemoperfusion have not been
177 established as beneficial for an overdose of glucagon; it is extremely unlikely that one of these
178 procedures would ever be indicated.

179 DOSAGE AND ADMINISTRATION

180 General Instructions for Use:

- 181 • The diluent is provided for use only in the preparation of glucagon for parenteral injection
182 and for no other use.
- 183 • Glucagon should not be used at concentrations greater than 1 mg/mL (1 unit/mL).
- 184 • Reconstituted glucagon should be used immediately. **Discard any unused portion.**
- 185 • Reconstituted glucagon solutions should be used only if they are clear and of a water-like
186 consistency.
- 187 • Parenteral drug products should be inspected visually for particulate matter and discoloration
188 prior to administration.

189 Directions for Treatment of Severe Hypoglycemia:

190 Severe hypoglycemia should be treated initially with intravenous glucose, if possible.

- 191 1. If parenteral glucose can not be used, dissolve the lyophilized glucagon using the
 192 accompanying diluting solution and use immediately.
 193 2. For adults and for pediatric patients weighing more than 44 lb (20 kg), give 1 mg (1 unit)
 194 by subcutaneous, intramuscular, or intravenous injection.
 195 3. For pediatric patients weighing less than 44 lb (20 kg), give 0.5 mg (0.5 unit) or a dose
 196 equivalent to 20 to 30 $\mu\text{g}/\text{kg}$.²⁻⁵
 197 **4. Discard any unused portion.**
 198 5. An unconscious patient will usually awaken within 15 minutes following the glucagon
 199 injection. If the response is delayed, there is no contraindication to the administration of
 200 an additional dose of glucagon; however, in view of the deleterious effects of cerebral
 201 hypoglycemia emergency aid should be sought so that parenteral glucose can be given.
 202 6. After the patient responds, supplemental carbohydrate should be given to restore liver
 203 glycogen and to prevent secondary hypoglycemia.

204 Directions for Use as a Diagnostic Aid:

205 Dissolve the lyophilized glucagon using the accompanying diluting solution and use
 206 immediately. **Discard any unused portion.**

207 The doses in the following table may be administered for relaxation of the stomach, duodenum,
 208 and small bowel, depending on the onset and duration of effect required for the examination.
 209 Since the stomach is less sensitive to the effect of glucagon, 0.5 mg (0.5 units) IV or 2 mg
 210 (2 units) IM are recommended.

Dose	Route of Administration	Time of Onset of Action	Approximate Duration of Effect
0.25-0.5 mg (0.25-0.5 units)	IV	1 minute	9-17 minutes
1-mg (1 unit)	IM	8-10 minutes	12-27 minutes
2 mg*(2 units)	IV	1 minute	22-25 minutes
2 mg*(2 units)	IM	4-7 minutes	21-32 minutes

211 *Administration of 2 mg (2 units) doses produces a higher incidence of nausea and vomiting than do lower doses.
 212

213 For examination of the colon, it is recommended that a 2 mg (2 units) dose be administered
 214 intramuscularly approximately 10 minutes prior to the procedure. Colon relaxation and reduction
 215 of patient discomfort may allow the radiologist to perform a more satisfactory examination.

216 HOW SUPPLIED

217 Glucagon Emergency Kit for Low Blood Sugar (Glucagon for Injection [rDNA origin])
 218 (MS8031):

219 1 mg (1 unit) — (VL7529), with 1 mL of diluting solution (Hyporet[®]* HY7530) (1s)
 220 NDC 0002-8031-01

221 Glucagon Diagnostic Kit (Glucagon for Injection [rDNA origin]) (MS8085):

222 1 mg (1 unit) — (VL7529), with 1 mL of diluting solution (Hyporet[®]* HY7530) (1s)
 223 NDC 0002-8085-01 (available in US market only).
 224

225 *Hyporet[®] (disposable syringe, Lilly).

226 Stability and Storage:

227 Before Reconstitution — Vials of Glucagon, as well as the Diluting Solution for Glucagon,
 228 may be stored at controlled room temperature 20° to 25°C (68° to 77°F)[see USP].

229 The USP defines controlled room temperature by the following: A temperature maintained
 230 thermostatically that encompasses the usual and customary working environment of 20° to 25°C
 231 (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and

232 that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in
233 pharmacies, hospitals, and warehouses.

234 After Reconstitution — Glucagon for Injection (rDNA origin) should be used immediately.

235 **Discard any unused portion.**

236 REFERENCES

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258 **INFORMATION FOR THE USER**

259 **GLUCAGON**

260 **FOR INJECTION**

261 **(rDNA ORIGIN)**

262
263 **BECOME FAMILIAR WITH THE FOLLOWING INSTRUCTIONS BEFORE AN**
264 **EMERGENCY ARISES. DO NOT USE THIS KIT AFTER DATE STAMPED ON THE**
265 **BOTTLE LABEL. IF YOU HAVE QUESTIONS CONCERNING THE USE OF THIS**
266 **PRODUCT, CONSULT A DOCTOR, NURSE OR PHARMACIST.**

267 Make sure that your relatives or close friends know that if you become unconscious, medical
268 assistance must always be sought. Glucagon may have been prescribed so that members of your
269 household can give the injection if you become hypoglycemic and are unable to take sugar by
270 mouth. If you are unconscious, glucagon can be given while awaiting medical assistance.

271 Show your family members and others where you keep this kit and how to use it. They need to
272 know how to use it before you need it. They can practice giving a shot by giving you your normal
273 insulin shots. It is important that they practice. A person who has never given a shot probably
274 will not be able to do it in an emergency.

275 **IMPORTANT**

- 276 • Act quickly. Prolonged unconsciousness may be harmful.
- 277 • These simple instructions will help you give glucagon successfully.

- 278 • Turn patient on his/her side to prevent patient from choking.
279 • The contents of the syringe are inactive. You must mix the contents of the syringe with the
280 glucagon in the accompanying bottle before giving injection. (*See DIRECTIONS FOR USE*
281 *below.*)
282 • Do not prepare Glucagon for Injection until you are ready to use it.
283 **WARNING: THE PATIENT MAY BE IN A COMA FROM SEVERE**
284 **HYPERGLYCEMIA (HIGH BLOOD GLUCOSE) RATHER THAN HYPOGLYCEMIA.**
285 **IN SUCH A CASE, THE PATIENT WILL NOT RESPOND TO GLUCAGON AND**
286 **REQUIRES IMMEDIATE MEDICAL ATTENTION.**

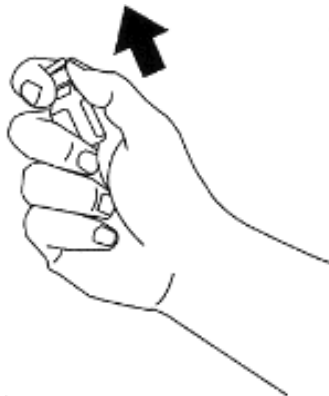
INDICATIONS FOR USE

287 Use glucagon to treat insulin coma or insulin reaction resulting from severe hypoglycemia (low
288 blood sugar). Symptoms of severe hypoglycemia include disorientation, unconsciousness, and
289 seizures or convulsions. Give glucagon if (1) the patient is unconscious (2) the patient is unable
290 to eat sugar or a sugar-sweetened product (3) the patient is having a seizure, or (4) repeated
291 administration of sugar or a sugar-sweetened product such as a regular soft drink or fruit juice
292 does not improve the patient's condition. Milder cases of hypoglycemia should be treated
293 promptly by eating sugar or a sugar-sweetened product. (*See INFORMATION ON*
294 *HYPOGLYCEMIA* below for more information on the symptoms of hypoglycemia.) Glucagon is
295 not active when taken orally.
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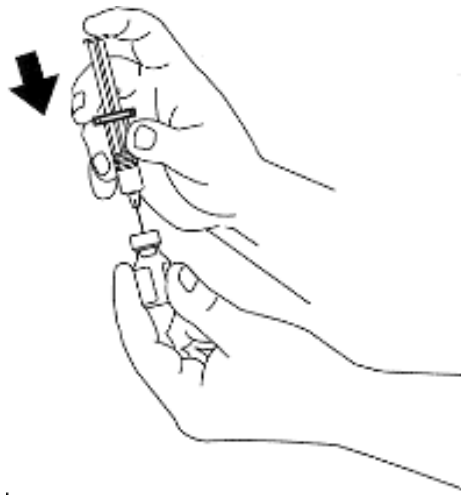
DIRECTIONS FOR USE

TO PREPARE GLUCAGON FOR INJECTION

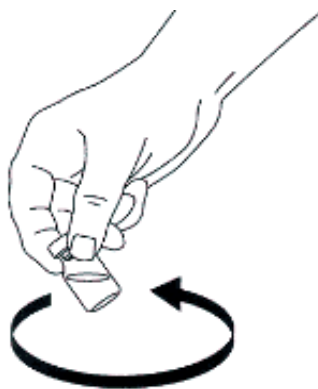
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299 1. Remove the flip-off seal from the bottle of glucagon. Wipe rubber stopper on bottle with
300 alcohol swab.



- 301 2. Remove the needle protector from the syringe, and inject the entire contents of the syringe
302 into the bottle of glucagon. **DO NOT REMOVE THE PLASTIC CLIP FROM THE**
303 **SYRINGE.** Remove syringe from the bottle.



- 304 3. Swirl bottle gently until glucagon dissolves completely. **GLUCAGON SHOULD NOT BE**
305 **USED UNLESS THE SOLUTION IS CLEAR AND OF A WATER-LIKE**
306 **CONSISTENCY.**

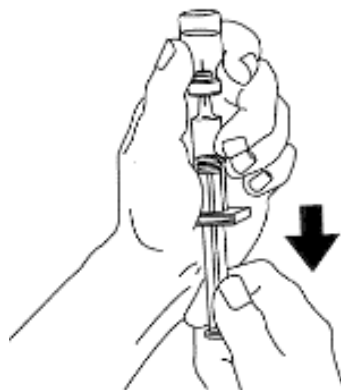


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TO INJECT GLUCAGON

Use Same Technique as for Injecting Insulin

- Using the same syringe, hold bottle upside down and, making sure the needle tip remains in solution, gently withdraw all of the solution (1 mg mark on syringe) from bottle. The plastic clip on the syringe will prevent the rubber stopper from being pulled out of the syringe; however, if the plastic plunger rod separates from the rubber stopper, simply reinsert the rod by turning it clockwise. The usual adult dose is 1 mg (1 unit). For children weighing less than 44 lb (20 kg), give 1/2 adult dose (0.5 mg). For children, withdraw 1/2 of the solution from the bottle (0.5 mg mark on syringe). **DISCARD UNUSED PORTION.**



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USING THE FOLLOWING DIRECTIONS, INJECT GLUCAGON IMMEDIATELY AFTER MIXING.

- Cleanse injection site on buttock, arm, or thigh with alcohol swab.
- Insert the needle into the loose tissue under the cleansed injection site, and inject all (or 1/2 for children weighing less than 44 lb) of the glucagon solution. **THERE IS NO DANGER OF OVERDOSE.** Apply light pressure at the injection site, and withdraw the needle. Press an alcohol swab against the injection site.
- Turn the patient on his/her side. When an unconscious person awakens, he/she may vomit. Turning the patient on his/her side will prevent him/her from choking.
- FEED THE PATIENT AS SOON AS HE/SHE AWAKENS AND IS ABLE TO SWALLOW.** Give the patient a fast-acting source of sugar (such as a regular soft drink or fruit juice) and a long-acting source of sugar (such as crackers and cheese or a meat sandwich). If the patient does not awaken within 15 minutes, give another dose of glucagon and **INFORM A DOCTOR OR EMERGENCY SERVICES IMMEDIATELY.**
- Even if the glucagon revives the patient, his/her doctor should be promptly notified. A doctor should be notified whenever severe hypoglycemic reactions occur.

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INFORMATION ON HYPOGLYCEMIA

Early symptoms of hypoglycemia (low blood glucose) include:

- sweating
- dizziness
- palpitation
- tremor
- hunger
- restlessness
- tingling in the hands, feet, lips, or tongue
- lightheadedness
- inability to concentrate
- drowsiness
- sleep disturbances
- anxiety
- blurred vision
- slurred speech
- depressed mood
- irritability
- abnormal behavior
- unsteady movement

- 344 • headache • personality changes
 345 If not treated, the patient may progress to severe hypoglycemia that can include:
 346 • disorientation • seizures
 347 • unconsciousness • death

348 The occurrence of early symptoms calls for prompt and, if necessary, repeated administration
 349 of some form of carbohydrate. Patients should always carry a quick source of sugar, such as
 350 candy mints or glucose tablets. The prompt treatment of mild hypoglycemic symptoms can
 351 prevent severe hypoglycemic reactions. If the patient does not improve or if administration of
 352 carbohydrate is impossible, glucagon should be given or the patient should be treated with
 353 intravenous glucose at a medical facility. Glucagon, a naturally occurring substance produced by
 354 the pancreas, is helpful because it enables the patient to produce his/her own blood glucose to
 355 correct the hypoglycemia.

356 POSSIBLE PROBLEMS WITH GLUCAGON TREATMENT

357 Severe side effects are very rare, although nausea and vomiting may occur occasionally.

358 A few people may be allergic to glucagon or to one of the inactive ingredients in glucagon, or
 359 may experience rapid heart beat for a short while.

360 If you experience any other reactions which are likely to have been caused by glucagon, please
 361 contact your doctor.

362 STORAGE

363 Before dissolving glucagon with diluting solution — Store the kit at controlled room
 364 temperature between 20° to 25°C (68° to 77°F).

365 After dissolving glucagon with diluting solution — Should be used immediately. **Discard any**
 366 **unused portion.** Solutions should be clear and of a water-like consistency at time of use.

367 Literature revised XXX, 2003

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