

How should I use Glucagon?

- Read the attached instructions for Use that come with Glucagon.
- Use Glucagon exactly as your doctor tells you to.
- Make sure that you and your family know how to use Glucagon the right way before you need it.
- Act quickly. Having very low blood sugar for a period of time may be harmful.
- Call for emergency medical help right after you use Glucagon.**
- If the person does not respond after 15 minutes, another dose may be given, if available.
- Eat sugar or a sugar sweetened product such as a regular soft drink or fruit juice as well as you are able to swallow.
- Tell your doctor each time you use Glucagon. Your doctor may need to change the dose of your diabetes medicines.

What are the possible side effects of Glucagon?
Glucagon may cause serious side effects, including:

- High blood pressure:** Glucagon can cause high blood pressure in certain people with heart or other serious conditions.
- Low blood sugar:** Glucagon can cause low blood sugar in patients with heart or other serious conditions and Glucagon may be making too much insulin in the body.
- Serious allergic reactions:** Call your doctor or get medical help right away if you have a serious allergic reaction including:
 - skin rash
 - difficulty breathing
 - low blood pressure
- High blood sugar:** If you receive Glucagon before your diabetes team if you cannot take high blood sugar. Your doctor will monitor your blood sugar levels during your treatment.
- Heart problems:** If you have heart problems and receive Glucagon before your diabetes team, you may have an increase in your blood pressure and pulse while using Glucagon which could be life threatening. Your doctor will monitor your heart during treatment.

The most common side effects of Glucagon include:

- nausea at the injection site
- stomach pain
- headache
- diarrhea
- itching at the injection site
- low potassium
- joint pain
- swelling
- diarrhea
- nausea
- headache
- irregular or abnormal heartbeats

Call your doctor if you have any side effects that bother you or that you are worried about. There are not all of the possible side effects of Glucagon. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-438-0235.

How should I store Glucagon?
Before you use the Glucagon powder and liquid:

- Store Glucagon at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 months (2 years).
- Do not freeze Glucagon.
- Keep Glucagon in its original package between 68°F and 77°F.

After you mix the Glucagon powder and liquid:

- Use Glucagon right away.
- Throw away any unused Glucagon.
- Glucagon should be clear and colorless. Do not use Glucagon if it is cloudy or if you see particles in the solution.

Keep Glucagon and all medicines out of the reach of children.

General information about the safe and effective use of Glucagon:
 Instructions are sometimes provided for hospital use. Read these labels on a Patient Information Leaflet. Do not use Glucagon for a condition for which it was not prescribed. Do not give Glucagon to other people, even if they have the same group. Some that use have, it may harm them. You can ask your pharmacist or healthcare provider for information about Glucagon from a written health professional.

What are the ingredients in the Glucagon?
Active ingredients: include monobasic and dibasic salts for reconstitution. For more information, go to www.fresenius-kabi.com or call 1-800-521-7774.

This Patient Information has been approved by the U.S. Food and Drug Administration. Approved: 06/2019

Instructions for Use
Glucagon (100/2.4 mg)
 for Injection, for subcutaneous, intramuscular or intravenous use

Read this Instructions for Use before you start using Glucagon and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment. Talk to your doctor or pharmacist if you have any questions about how to use Glucagon.

Important:

- Read and become familiar with this Instructions for Use before an emergency happens.**
- Share your family medical and all other health care with your Glucagon Emergency Kit for Low Blood Sugar and how to use it the right way.
- Call for emergency medical help right after you use Glucagon.
- Do not share your Glucagon syringe or needles with another person. You may give other people a serious infection if you provide them a glucose injection from you.
- The prefilled syringe that comes with your Glucagon Emergency Kit for Low Blood Sugar is meant for use with Glucagon only. Do not use Glucagon syringe to inject other medicines.

How should I store Glucagon?
 Before you use the Glucagon powder and liquid:

- Store Glucagon at room temperature between 68°F to 77°F (20°C to 25°C). Do not refrigerate, freeze or heat Glucagon. Do not use Glucagon if the expiration date has passed.
- Do not freeze Glucagon.
- Keep Glucagon in its original package and Glucagon out of sight.

After you mix the Glucagon powder and liquid:

- Use Glucagon right away.
- Throw away any unused Glucagon.
- Glucagon should be clear and colorless. Do not use Glucagon if it is cloudy or if you see particles in the solution.

Supplies you will need for your Glucagon injection (See Figure 1):

- 1 Glucagon Emergency Kit for Low Blood Sugar that contains:
 - 1 kit that contains 1 mg of Glucagon for injection and 1 prefilled glass syringe with attached needle that contains 1 mL of Sterile Water for Injection.



1 patient resistant container for throwing away used needles and syringes. See the disposal process of (throw away) used Glucagon prefilled syringe at the end of these instructions.

Common injection sites for Glucagon are upper arms, thighs, or buttocks.

Caution: Patient does not need to be lying down to administer Glucagon. As long as the common injection sites can be easily accessed, they can be easily accessed.

Step 1. Using your thumb, lift the orange plastic cap off the Glucagon vial (See Figure 2).

- 1 patient resistant container for throwing away used needles and syringes. See the disposal process of (throw away) used Glucagon prefilled syringe at the end of these instructions.
- Common injection sites for Glucagon are upper arms, thighs, or buttocks.
- Caution: Patient does not need to be lying down to administer Glucagon. As long as the common injection sites can be easily accessed, they can be easily accessed.

Step 2. Pick up the prefilled syringe, containing sterile water. Hold the syringe with your thumb and index finger. Use your other hand to peel the needle cover off the syringe (See Figure 3).

- Do not remove the plastic backstop from the syringe.

Step 3. Pick up the Glucagon vial. Hold the vial of dry powder with 1 hand and with your other hand push the needle of the prefilled syringe through the center of the rubber stopper (See Figure 4).

Step 4. Hold the vial and syringe together, with the needle still inserted into the vial. Carefully turn the vial and syringe together right side up. Squeeze the plunger down until the air/foam is empty (See Figure 5).

- Do not take the syringe out of the vial.

Step 5. Hold the entire unit (the vial and syringe) in 1 hand and gently shake the mix until the powder is completely dissolved (See Figure 6).

- Do not use if it is cloudy or if you see particles in the solution.
- Do not take the syringe out of the vial.

Step 6. Firmly hold the vial and syringe together, with the needle still inserted into the vial. Carefully turn the vial and syringe together upside down. Gently tap and down on the plunger and slowly withdraw all of the liquid into the syringe (See Figure 7).

- Do not pull the plunger out of the syringe.

Step 7. Keep the needle inside the vial. Check the syringe for air bubbles. If you see bubbles, tap the syringe with the bubble side to the top of the syringe (See Figure 8).

- Gently push on the plunger to move only the air bubbles back into the vial.

Step 8. Hold the vial and syringe, as shown (See Figure 9).

Giving the Glucagon for Injection:

Step 8. Choose the injection site (See Figure 10).

Common injection sites for Glucagon are upper arms, thighs, or buttocks.

Caution: Patient does not need to be lying down to administer Glucagon. As long as the common injection sites can be easily accessed, they can be easily accessed.

Step 9. With 1 hand gently pinch the skin at the injection site. With your other hand, insert the needle into the skin and push the syringe against the skin until the syringe is empty (See Figure 11).

After Giving the Glucagon Injection:

Step 11. Pull the needle out (See Figure 12).

Use a gentle tug on the ball (not included in the kit) if needed to press the needle into the skin to make sure there is no direct contact with the skin.

Step 12. Turn the person on their side. When an unconscious person awakes, they may vomit. Turning the person on their side will lessen the chance of choking.

Step 13. Call for emergency medical help right away, if the person does not respond after 15 minutes, another dose may be given, if available.

Step 14. Feed the person as soon as they are awake and able to swallow.

Give the person a fast acting source of sugar (such as a regular soft drink or fruit juices) and a long acting source of sugar (such as crackers and cheese) or a meal soon after.

Step 15. Even if the Glucagon for Injection treatment wakes the person, tell their doctor right away. The doctor should be told whenever a severe drop in blood sugar (hypoglycemia reaction) happens. The person's dose of diabetes medicine may need to be changed.

Hypoglycemia may happen again after receiving Glucagon for Injection treatment.

Early symptoms of hypoglycemia may include:

- headache
- irritability
- depressed mood
- diarrhea
- irritability in the hands, feet, lips, or tongue
- sleep disturbance
- irregularly
- irregular heartbeat (palpitations)
- anxiety
- light-headedness
- nausea
- irritability
- difficulty to concentrate
- blurred vision
- personality changes
- slurred speech
- headache

If not treated early, hypoglycemia may worsen and the person may have severe hypoglycemia. Signs of severe hypoglycemia include:

- confusion
- seizures
- unconsciousness
- death

How should I dispose of (throw away) Glucagon pre-filled syringes?

Put used syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. Do not place your sharps disposal container in your regular household trash. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/ohrt/sharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Keep Glucagon and all medicines out of the reach of children.
 This Instructions for Use has been approved by the U.S. Food and Drug Administration. Approved: 06/2019
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Glucagon Kit

Table 4 Pharmacodynamic Properties of Another Glucagon for Injection Product for Intravenous Route

Route of Administration	Dose	Time of Maximal Glucose Concentration	Time of Onset of Action for GI Smooth Muscle Inhibition	Duration of Smooth Muscle Inhibition
Intravenous	0.5 to 1.0 mg	15 to 30 minutes	45 minutes	3 to 11 minutes

Gluc is determined based on the length of the procedure.

Table 5 Pharmacodynamic Properties of Another Glucagon for Injection Product for Intramuscular Route

Route of Administration	Dose	Time of Maximal Glucose Concentration	Time of Onset of Action for GI Smooth Muscle Inhibition	Duration of Smooth Muscle Inhibition
Intramuscular	1 mg	30 to 45 minutes	1 to 3 minutes	11 to 32 minutes

Gluc is determined based on the length of the procedure.

In a study in healthy subjects, a subcutaneous dose of 1 mg Glucagon for Injection resulted on average a peak blood glucose concentration of 79.3 mg/dL with a median time of 30 minutes after injection.

12.3 Pharmacokinetics

Maximum
Subcutaneous administration of Glucagon for Injection, the median time to reach the maximum blood glucose concentration of 79.3 mg/dL was approximately 30 to 45 minutes after subcutaneous administration of 1 mg dose. The maximum blood glucose concentration of 79.3 mg/dL was attained approximately 15 minutes after dosing.

Half-life
The mean apparent half-life of glucagon was about 42 minutes after subcutaneous administration, the mean apparent half life of glucagon was 26 minutes after intramuscular administration.

Metabolism
Glucagon is degraded in the liver, kidney, and plasma.

13. TOXICOLOGICAL INFORMATION

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis
Long term studies in animals to evaluate carcinogenic potential have not been performed.

Mutagenesis
Synthetic glucagon was negative in the bacterial reverse mutation assay (Ames test). The clastogenic potential of synthetic glucagon in the Chinese Hamster Ovary (CHO) assay was positive in the absence of metabolic activation. Doses of 100 and 200 mg/kg of Glucagon for Injection and recombinant origin gave slightly higher incidences of micronucleated binucleated cells than those seen in effect in females. The weight of evidence indicates that synthetic and recombinant glucagon are not relevant and do not pose a genotoxic risk to humans.

Impairment of fertility
Glucagon was not tested in animal fertility studies. Studies in man have shown that pancreatic glucagon does not cause impaired fertility.

14. HOW SUPPLIED/STORAGE AND HANDLING

14.1 How Supplied
Glucagon for Injection is supplied as a sterile, lyophilized white powder, available in vials.

Presentation	NDC	Strength	Description
Glucagon Emergency Kit for Low Blood Sugar	03123-042-01	1 mg per vial	1 mL single-dose vial of Glucagon for Injection (1 mg/mL) and 1 single-dose vial of Sterile Water for Injection, USP for reconstitution

Use as a Diagnostic Kit	NDC	Strength	Description
10 Single-Dose Vials	03123-096-01	1 mg per vial	1 mL single-dose vial of Glucagon for Injection
Diagnostic Kit	03123-093-03	1 mg per vial	1 mL single-dose vial of Glucagon for Injection and 1 mL single-dose vial of Sterile Water for Injection, USP for reconstitution

14.2 Recommended Storage

Refrigeration
The package containing Glucagon for Injection vials may be stored up to 24 months at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature] prior to reconstitution. Do not freeze. Keep in the original package to protect from light.

After Reconstitution
Use the reconstituted glucagon solution immediately. Discard any unused portion (see Dosage and Administration 2.2).

17. PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use), **Reconstitution of Another Glucagon**, and **Instructions for Use**.
Inform patient and family members or caregivers on how to recognize the signs and symptoms of severe hypoglycemia and the risks of prolonged hypoglycemia.

Administration
Review the Patient Information and Instructions for Use with the patient and family members or caregivers.

Safety Information
Inform patients that drug reactions can occur with Glucagon for Injection. Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions (see Warnings and Precautions 5.2).

What are the ingredients in the Glucagon?
Glucagon (5000 IU/kg) and water for injection, the excipients, intramuscular or intravenous use.

What is Glucagon?

Glucagon is a pancreatic hormone used:
• to treat very low blood sugar (severe hypoglycemia) in people with diabetes.
• to treat very low blood sugar (severe hypoglycemia) in patients receiving cardiac surgery.

Who should not use Glucagon?
Do not use Glucagon if:
• you have a tumor in the gland on top of your kidneys (adrenal gland) called a pheochromocytoma.
• you have a heart or lung circulation problem.

Who should use Glucagon with caution?
You should use Glucagon with caution if you have:
• a heart or lung circulation problem.
• a history of seizures.
• a history of diabetes.
• a history of low blood sugar (hypoglycemia).
• a history of low blood sugar (hypoglycemia) during surgery.

What should you tell your doctor before using Glucagon?
Before using Glucagon, tell your doctor about all of your medical conditions, including if you:
• have diabetes problems.
• have not had food or water for a long time (prolonged fasting or starvation).
• have low blood sugar that does not go away (chronic hypoglycemia).
• are taking any other medicines.
• are taking any other medicines for a long time (chronic use).
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How should I store Glucagon?
Before you mix the Glucagon powder and liquid:
• Store Glucagon for Injection in the original package (Glucagon and out of light).
• After you mix the Glucagon powder and liquid:
• Use Glucagon right away.
• Store any unused Glucagon.
• Glucagon should be clear and colorless. Do not use Glucagon if it is cloudy or if you see particles in the solution.
• Use Glucagon all medicine part of the inside of the vial.

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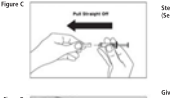
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Step 1. Using your thumb, flip the orange plastic cap off the Glucagon vial (See Figure B).



Step 2. Pick up the pre-filled syringe containing sterile water. Hold the syringe with 1 hand and with your other hand pull the needle cover off the syringe (See Figure C).



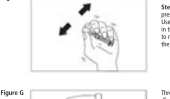
Step 3. Pick up the Glucagon vial. Hold the vial of dry powder with 1 hand and with your other hand push the needle of the pre-filled syringe through the center of the rubber stopper (See Figure D).



Step 4. Hold the vial and syringe together, with the needle still inserted into the vial. Carefully turn the vial and syringe together (right side up). Slowly push the plunger down until the syringe is empty (See Figure E).



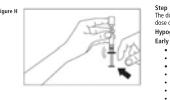
Step 5. Hold the entire unit (the vial and syringe) in 1 hand and gently shake the vial until the powder is completely dissolved (See Figure F).



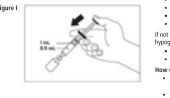
Step 6. First, hold the vial and syringe together, with the needle still inserted into the vial. Carefully turn the vial and syringe together (right side up). Slowly push the plunger down until the syringe is empty (See Figure G).



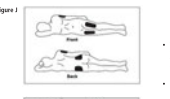
Step 7. Push the needle back into the vial. Check the syringe for air bubbles. If you see bubbles, tap the syringe until the bubbles rise to the top of the syringe (See Figure H). Gently push on the plunger to move only the air bubbles back into the vial.



Step 8. Hold the vial and syringe as shown (See Figure I).



Step 9. Gently draw the injection site (See Figure J).



Step 10. With 1 hand gently pinch the skin at the injection site. With your other hand insert the needle into the skin and push the syringe plunger down until the syringe is empty (See Figure K).



After Giving the Glucagon Injection:

Step 11. Pull the needle out of the skin and press on the injection site (See Figure L).



Step 12. Turn the person on their side. When an unconscious person awakes, they may vomit. Turning the person on their side will lessen the chance of choking.

Step 13. Call for emergency medical help right away if the person does not respond after 15 minutes, another dose may be given, if available.

Step 14. Feed the person as soon as they are awake and able to swallow. Give the person a lot of sipping water or sugar (such as a regular soft drink or fruit juice) and a long acting source of sugar (such as crackers and bread or meat sandwich).

Step 15. Even if the Glucagon for Injection treatment wakes the person, tell their doctor right away. The doctor should be told whenever a severe drop in blood sugar (hypoglycemia reaction) happens. The person's dose of diabetic medicine may need to be changed.

Early symptoms of hypoglycemia may include:

- sweating
- weakness
- dizziness
- slow heartbeat
- irregular heartbeat (palpitation)
- anxiety
- tremor
- blurred vision
- hunger
- slurred speech
- restlessness
- sluggishness
- irritability
- abnormal behavior
- light-headedness
- unsteady movement
- inability to concentrate
- personality changes
- headache

If not treated early, hypoglycemia may worsen and the person may have severe hypoglycemia. Signs of severe hypoglycemia include:

- confusion
- seizures
- death

How should I dispose of three empty Glucagon pre-filled syringes?

- Put used syringes in a FDA cleared sharps disposal container right away after use. Do not throw away Glucagon or three needles and syringes in your household trash.
- If you do not have a FDA cleared sharps disposal container, you may use a household container that is:
• made of heavy plastic,
• can be closed with a tight fitting, puncture resistant lid, without caps being able to come out,
• upright and leak-proof, and,
• non-recyclable and
• clearly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be cities or local laws about how you should dispose away needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the case that you live in, go to the FDA's website at: <http://www.fda.gov/ohrt/sharpsdisposal>.

Do not dispose of any used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

Keep Glucagon and all medicines out of the reach of children.

This information for Use has been approved by the U.S. Food and Drug Administration. Approved 09/2019

The brand names mentioned in this document are the trademarks of their respective owners.

Manufactured by:
Fresenius Kabi
Lake Zurich, IL 60057

FRESENIUS KABI

www.fresenius-kabi.com/us

XXXXXX

Glucagon
for Injection
(Synthetic)

509813

1 mg per vial

For subcutaneous,
intramuscular or
intravenous injection.

Reconstitute with Sterile Water
for Injection, USP Rx only

Glucagon 1 mg

Fresenius Kabi

XXXXXX

LOT/EXP



3 63323-583-13 2



IMPORTANT: Read the enclosed insert carefully for directions before using.

Each vial of Glucagon for Injection contains:
Glucagon.....1 mg
Lactose.....107 mg
Hydrochloric acid and/or sodium hydroxide (to adjust pH)

Each Prefilled Syringe contains:
Sterile Water for Injection, USP.....1 mL
- for use as diluent

Usual dose: 1 mg per vial for subcutaneous, intramuscular or intravenous injection in adults and pediatric patients (55 lbs or greater).

Smaller pediatric patients see enclosed insert.

Mix immediately before use.

Add the entire content of the accompanying syringe of Sterile Water for Injection, USP into the Glucagon for Injection vial.

Mix well and gently withdraw the entire content of the vial back into the syringe.

NON-RETURNABLE

Before Reconstitution: Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature]. Protect from light.

After Reconstitution: Should be used immediately. **Discard unused portion.**

XXXXXX



N(01)20363323582825

www.fresenius-kabi.com/us

GTIN: 00363323593032

1 mg per vial
for Injection
(Synthetic)
Glucagon

509603

NDC 63323-593-03

509603

Glucagon for Injection (Synthetic)

1 mg per vial

Each vial of Glucagon for Injection contains:

Glucagon1 mg
Lactose107 mg
Hydrochloric acid and/or
Sodium hydroxide (to adjust pH)

Each Diluent vial contains:

Sterile Water for Injection, USP1 mL

Usual dosage: See package insert.



3 63323-593-03 2



Glucagon for Injection (Synthetic)

1 mg per vial



Lake Zurich, IL 60047

www.fresenius-kabi.com/us

NDC 63323-593-03

509603

Glucagon for Injection (Synthetic)

1 mg per vial

For intramuscular or intravenous injection only.

FOR DIAGNOSTIC USE ONLY.

Reconstitute with Sterile Water for Injection, USP
immediately before use.

Each kit contains:

- One single dose vial with 1 mg of Glucagon for Injection
- One single dose vial with 1 mL of Sterile Water for Injection, USP

Single Dose Vials
Rx only



3 63323-593-03 2

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Glucagon for Injection (Synthetic)

1 mg per vial

STORE AT: 20° to 25°C (68° to 77°F) [see USP Controlled Room
Temperature]. Protect from
light. Discard unused portion.
Do not freeze.

Do not store for later use.

The container closure is not
made with natural rubber latex.

Single Dose Vials
Rx only

Glucagon 509603
for Injection
(Synthetic)

1 mg per vial

For intramuscular or
intravenous injection.

For diagnostic use only.

Reconstitute with Sterile Water
for Injection, USP Rx only

Glucagon 1 mg

Fresenius Kabi

XXXXXXXXXX

LOT/EXP



3 NDC 63323-596-03 3

NDC 63323-596-13

Glucagon for Injection (Synthetic)

1 mg per vial

For intramuscular or
intravenous injection only.
For diagnostic use only.

10 Vials

Rx only

TO BE SOLD ONLY AS AN UNBROKEN PACKAGE

Glucagon 1 mg, Lactose 107 mg. Hydrochloric acid and/or sodium hydroxide (to adjust pH).

Keep out of reach of children.

STORE AT: 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Do Not Freeze, protect from light. Glucagon for Injection should be reconstituted with 1 mL Sterile Water for Injection, USP immediately before use. Do not store for later use. Read the enclosed insert before use.

The container closure is not made with natural rubber latex.

509613



Fresenius Kabi
Lake Zurich, IL 60047



XXXXXXX



(01)20363323596136

Glucagon
for Injection
(Synthetic)

509613

1 mg per vial

For intramuscular or
intravenous injection.

For diagnostic use only.

Reconstitute with Sterile Water
for Injection, USP Rx only

Glucagon 1 mg

Fresenius Kabi
Lake Zurich, IL 60047

XXXXXXXXXX

LOT/EXP



3 NDC 63323-596-11 8



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari
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