

**OROXID FORTE ORAL HYGIENE- hydrogen peroxide spray**  
**OROXID FORTE ORAL HYGIENE- hydrogen peroxide solution**  
**Innova Medical Group**

*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.*

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**Keep out of reach of children**

Keep away from children

forte

## ORAL HYGIENE SPRAY

### INNOVATIVE HELP WITH

- Gingivitis, periodontitis
- Inflammation of oral cavity
- Bleeding and irritated gums
- Intensive oral hygiene (fixed dental braces, prosthesis, implants)
- Reduction of deposit on the tongue
- Prevention of dental plaque
- Reduction of tooth stains
- Restoration of fresh breath



Read the instructions before use



Store at temperature of 5 °C to 25 °C



Protect from direct sunlight



Keep away from children



Avoid direct contact with eyes

### HOW TO USE

Use OROXID® forte two to three times a day preferably during or after brushing your teeth. Spray the solution into the oral cavity with 3 to 4 pressures of the spray, gargle for about 30 seconds and spit it out. Use OROXID® forte regularly, until the situation or elimination of inflammation improves.

OROXID® FORTE CONTAINS:  
deionized water, hydrogen peroxide  
30 g/kg, Actipone® PX3, flavors, stabilizer.

After activation of the spray the product is recommended to be used within 3 months.

e 100 ml



## **Storage and Handling**

Store at Temperature of 5°C to 25°C

Protect from Direct sunlight

**Ingestion**

When ingested **OROXID® forte** can cause mild irritation of the lining of the gastrointestinal tract, vomiting and diarrhea. When in quantities or the occurrence of severe symptoms consult with your doctor.

**Inhalation**

**OROXID® forte** at room temperature does not produce significant quantities of hydrogen peroxide vapors. When heated, disperse can lead to acute inhalation of hydrogen peroxide, which can cause irritation of the nose, throat and respiratory tract.

**Spill**

Do not open the container. If spills occur, and the solution comes into contact with skin, wash it off with soap and water. Wipe spill a sufficient amount of paper and then wash your hands.

**4. Ingredients**

**OROXID® forte** contains deionized water, 3 % hydrogen peroxide solution, Actipone® PX3 (Aqua, Glycerin, PEG-40 Hydrogenated Officialine Root Extract, Commiphora Myrrha Resin Extract, Echinacea Purpurea Extract), flavors and stabilizer.

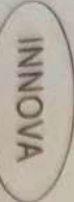
**5. Storage, shelf life**

Store **OROXID® forte** at room temperature of 5 °C to 25 °C. Shelf life of the product is two years.

After opening, it is recommended the product should be used within three months. Store away from direct sunlight.

Only use the product in the intact container. Keep out of reach of children.

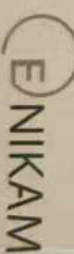
**Produced exclusively for:**



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Date of text revision: 05/2019 - V1.4

**Manufacturer:**



ENIKAM d.o.o.  
C. Andreja Bitenca 118  
1000 Ljubljana, Slovenia  
info@enikam-oxy.com

**Description of the symbols on**



Lot number



Reference number



Follow instructions for use



Use by: month and year



Storage (temperature)



Protect from direct sunlight

Manufacturer



## Warning

forte

# ORAL HYGIENE SPRAY

## INNOVATIVE HELP WITH

- Gingivitis, periodontitis
- Inflammation of oral cavity
- Bleeding and irritated gums
- Intensive oral hygiene (fixed dental braces, prosthesis, implants)
- Reduction of deposit on the tongue
- Prevention of dental plaque
- Reduction of tooth stains
- Restoration of fresh breath



Read the instructions before use



Store at temperature of 5 °C to 25 °C



Protect from direct sunlight



Keep away from children



Avoid direct contact with eyes

## HOW TO USE

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30 g/kg, Actipone® PX3, flavors, stabilizer.

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e 100 ml



Avoid direct contact with eyes

**Innovative Help With**

forte

## ORAL HYGIENE SPRAY

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Inflammation of oral cavity

Bleeding and irritated gums

Intensive oral hygiene(Fixed dental braces, prosthesis, implants)

Reduction of deposit on the tongue

Prevention of dental plaque

Reduction of tooth stains

Restoration of fresh breath

## **How to use**





## ORAL HYGIENE SPRAY

### INNOVATIVE HELP WITH

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deionized water, hydrogen peroxide  
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### Produced exclusively for:

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Manufacturer/Hersteller:

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[www.oroxid.com](http://www.oroxid.com)



Use OROXID Forte two to three times a day preferably during or after brushing your

teeth. Spray the solution into the oral cavity with 3 to 4 pressures of the spray, gargle for about 30 seconds and spit it out. Use OROXID forte regularly, until the situation of elimination of inflammation improves.

### **Dosage Administration**

3 to 4 pressure of the spray, two to three times a day

helps to restore fresh breath, reduce deposits on the tongue and usually induced by the presence of fungal and bacterial pathogens.

**OROXID® forte** acts only on the surface, the hydrogen peroxide does not penetrate into deeper tissues.

As an excipient **OROXID® forte** also contains Actipone® PX3 - an extract of herbs has a soothing effect on irritated and sensitive tissues in the oral cavity.

The product is available in the form of a 50 ml, 100 ml spray and a 30 ml, 150 ml and 250 ml solution pack for gargling.

## 2. Administration

Use **OROXID® forte** two to three times a day, preferably during or after brushing your teeth. **OROXID® forte oral spray**: spray the solution into the oral cavity with 3 to 4 pumps of the spray, gargle it for about 30 seconds and spit it out. **OROXID® forte oral solution**: pour approximately 20 ml of liquid (content of two cups) in to a glass, gargle it for about 30 seconds and spit it out.

Use **OROXID® forte** regularly to improve the situation or to remove the inflammation. If the situation does not improve, contact your doctor. **OROXID® forte** is not intended for the treatment of severe inflammatory diseases of the oral cavity, covering the deeper tissues. In this case, consult with your doctor. For preventive purposes and the maintenance of good oral cavity hygiene **OROXID® forte** is used once or twice a day in the manner as described above. The dispersion of the solution in the mouth can be felt as foam, this indicates the release of active oxygen.

## 3. Side effects and precautions

When applied to the mucosa hydrogen peroxide at low concentration rarely causes a feeling of irritation. In the case of a hypersensitive reaction or irritation discontinue use of the product. The feeling of irritation is transitory in nature and stops after a few minutes or after washing with water. **OROXID® forte** is only intended for an application in the oral cavity and gargling. **OROXID® forte** is not intended to be consumed. Avoid contact with eyes.

### Contact with eyes

Contact of **OROXID® forte** with the eyes may cause irritation, tearing and blurred vision, but serious injuries are unlikely. After contact with the eyes rinse the affected eye with tap water or saline solution and, if necessary, visit your doctor.

### Ingestion

When ingested **OROXID® forte** can cause mild irritation of the lining of the gastrointestinal tract, vomiting and diarrhea. When ingested in large quantities or the occurrence of severe symptoms consult with your doctor.

### Inhalation

**OROXID® forte** at room temperature does not produce significant quantities of hydrogen peroxide vapors. When heated, dispersion or solution can lead to acute inhalation of hydrogen peroxide, which can cause irritation of the nose, throat and respiratory tract.

### Spill

Do not open the container. If spills occur, and the solution comes into contact with skin, wash it off with soap and water. Wipe spilled solution with a sufficient amount of paper and then wash your hands.

## 4. Ingredients

**OROXID® forte** contains deionized water, 3 % hydrogen peroxide solution, Actipone® PX3 (Aqua, Glycerin, PEG-40 Hydrogenated Castor Oil, Zingiber Officinale Root Extract, Commiphora Myrrha Resin Extract, Echinacea Purpurea Extract), flavors and stabilizer.

## 5. Storage, shelf life

Store **OROXID® forte** at room temperature of 5 °C to 25 °C.

Shelf life of the product is two years.

## Purpose

forte

# ORAL HYGIENE SPRAY

## INNOVATIVE HELP WITH

- Gingivitis, periodontitis
- Inflammation of oral cavity
- Bleeding and irritated gums
- Intensive oral hygiene (fixed dental braces, prosthesis, implants)
- Reduction of deposit on the tongue
- Prevention of dental plaque
- Reduction of tooth stains
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Read the instructions before use



Store at temperature of 5 °C to 25 °C



Protect from direct sunlight



Keep away from children



Avoid direct contact with eyes

## HOW TO USE

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OROXID® FORTE CONTAINS:  
deionized water, hydrogen peroxide  
30 g/kg, Actipone® PX3, flavors, stabilizer.

After activation of the spray the product is recommended to be used within 3 months.

e 100 ml



**Active Ingredient**

Hydrogen peroxide



helps to restore fresh breath, reduce deposits on the tongue and usually induced by the presence of fungal and bacterial pathogens.

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## 5. Storage, shelf life

Store **OROXID® forte** at room temperature of 5 °C to 25 °C.  
Shelf life of the product is two years.

**Inactive ingredient**

deionized water

helps to restore fresh breath, reduce deposits on the tongue and usually induced by the presence of fungal and bacterial pathogens.

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## Indication and usage

forte

# ORAL HYGIENE SPRAY

### INNOVATIVE HELP WITH

- Gingivitis, periodontitis
- Inflammation of oral cavity
- Bleeding and irritated gums
- Intensive oral hygiene (fixed dental braces, prosthesis, implants)
- Reduction of deposit on the tongue
- Prevention of dental plaque
- Reduction of tooth stains
- Restoration of fresh breath



Read the instructions before use



Store at temperature of 5 °C to 25 °C



Protect from direct sunlight



Keep away from children



Avoid direct contact with eyes

### HOW TO USE

Use OROXID® forte two to three times a day preferably during or after brushing your teeth. Spray the solution into the oral cavity with 3 to 4 pressures of the spray, gargle for about 30 seconds and spit it out. Use OROXID® forte regularly, until the situation or elimination of inflammation improves.

OROXID® FORTE CONTAINS:  
deionized water, hydrogen peroxide  
30 g/kg, Actipone® PX3, flavors, stabilizer.

After activation of the spray the product is recommended to be used within 3 months.

e 100 ml



## Product Description



Instructions for use

English

## OROXID® forte — oral spray or oral solution

### 1. Product description

**OROXID® forte** is a solution used for maintaining of oral hygiene, healthy gums and to help in inflammatory conditions of the oral cavity. It is intended for the prevention and alleviation of diseases of periodontal tissues, such as irritated, inflamed and bleeding gums. It helps to reduce gingivitis, periodontitis, gum damage due to human intervention, such as tooth extraction. For the prevention of gingivitis and other inflammatory diseases of the oral cavity proper oral hygiene is essential. The development of gingivitis depends on the presence of plaque and bacteria.

**OROXID® forte**, due to its mechanical properties and release of oxygen in the form of a mild foaming of hydrogen peroxide, positively affects the microenvironment of the damaged mucosa. Therefore, it is recommended as a complementary oral hygiene for fixed dental appliances, partial dentures, fixed prosthetic substitutes (crowns, bridges) and implants. It improves the results of oral hygiene for patients undergoing orthodontic irregularities which interfere with normal dental hygiene. Hydrogen peroxide helps preventing the formation of plaque and tooth discoloration. It also helps to restore fresh breath, reduce deposits on the tongue and oral mucosa, usually induced by the presence of fungal and bacterial pathogens.

**OROXID® forte** acts only on the surface, the hydrogen peroxide does not penetrate into deeper tissues.

As an excipient **OROXID® forte** also contains Actipone® PX3 - an extract of herbs has a soothing effect on irritated and sensitive tissues in the oral cavity.

The product is available in the form of a 50 ml, 100 ml spray and a 30 ml, 150 ml and 250 ml solution pack for gargling.

### 2. Administration


Use **OROXID® forte** two to three times a day, preferably during or after brushing your teeth. **OROXID® forte oral spray**: spray the solution into the oral cavity with 3 to 4 pumps of the spray, gargle it for about 30 seconds and spit it out. **OROXID® forte oral solution**: pour approximately 20 ml of liquid (content of two cups) in to a glass, gargle it for about 30 seconds and spit it out.

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### 3. Side effects and precautions


# Active Ingredient

e 100 ml



3 830000 1215732






LOT


**OROXID®  
forte**


**ORAL HYGIENE**  
SPRAY


**INNOVATIVE HELP WITH**


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- Inflammation of oral cavity
- Bleeding and irritated gums
- Intensive oral hygiene (fixed dental braces, prosthesis, implants)
- Reduction of deposit on the tongue
- Prevention of dental plaque
- Reduction of tooth stains
- Restoration of fresh breath

 Read the instructions before use

 Store at temperature of 5 °C to 25 °C

 Protect from direct sunlight

 Keep away from children

 Avoid direct contact with eyes

**HOW TO USE:**

Use OROXID® forte two to three times a day preferably during or after brushing your teeth. Spray the solution into the oral cavity with 3 to 4 pressures of the spray, gargle for about 30 seconds and spit it out. Use OROXID® forte regularly, until the situation or elimination of inflammation improves.


OROXID® FORTE CONTAINS: deionized water, hydrogen peroxide 30 g/kg, Actipone® PX3, flavors, stabilizer.

After activation of the spray the product is recommended to be used within 3 months.


**OROXID®  
forte**

**ORAL HYGIENE**  
SPRAY

**HEALTHY &  
FRESH SMILE**




**ALCOHOL FREE  
CHLORHEXIDINE FREE**




**OROXID®  
forte**

**MUNDHYGIENE**  
SPRAY

**FRISCHES &  
GESUNDES LÄCHELN**



**ALKOHOLFREI  
CHLORHEXIDINEFREI**





**OROXID®  
forte**


**MUNDHYGIENE**  
SPRAY


**INNOVATIVE HILFE BEI**


- Zahnfleisch, Zungen und Schleimhautentzündung
- blutendem und gereiztem Zahnfleisch
- Intensive Mundhygiene (auch bei festen Zahnspangen, Prothesen, Implantaten)
- Verringerung des Zungenbelages
- Verhinderung von Zahnablagerungen
- Verringerung der Zahnverfärbung
- Wiederherstellung des frischen Atems

 Vor Gebrauch Beipackzettel lesen

 Lösung bei Temperatur von 5 °C bis 25 °C lagern

 Lösung vor direktem Licht schützen

 Für Kinder unzugänglich aufbewahren


 Augenkontakt vermeiden


**GEBRUCHSANWEISUNG**


OROXID® forte ist zwei bis drei Mal pro Tag, vorzugsweise bei und nach dem Zähneputzen, anzuwenden. Die Lösung sollte in die Mundhöhle (3-4 Dosen) gesprüht werden. Mit der Lösung ist ca. 30 Sekunden zu gurgeln und danach auszuspucken. OROXID® forte ist regelmäßig bis zur Beseitigung von Entzündungen zu verwenden.

OROXID® FORTE BEINHALTET: deionisiertes Wasser, Wasserstoffperoxid 30 g/kg, Actipone® PX3, Aromastoffe und Stabilisator.

Nach dem Öffnen wird empfohlen, das Produkt innerhalb von drei Monaten zu verbrauchen.

 Manufacturer/Hersteller:

 ENIKAM d.o.o.  
C. Andreja Bitenca 118  
1000 Ljubljana, Slovenia  
info@enikam.com  
www.oxid.com



**Package Label**

**Main panel**





## ORAL HYGIENE SPRAY

### INNOVATIVE HELP WITH

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deionized water, hydrogen peroxide  
30 g/kg, Actipone® PX3, flavors, stabilizer

### Produced exclusively for:

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Manufacturer/Hersteller:

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[www.oroxid.com](http://www.oroxid.com)



# Package label princile Display



SPRAY  
ORAL HYGIENE  
OROXID<sup>®</sup>  
forte

OROXID<sup>®</sup>  
forte

ORAL HYGIENE  
SPRAY

#### INNOVATIVE HELP WITH

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- Restoration of fresh breath



Read the instructions before use



Store at temperature of 5 °C to 25 °C



Protect from direct sunlight



Keep away from children



Avoid direct contact with eyes

#### HOW TO USE:

Use OROXID<sup>®</sup> forte two to three times a day preferably during or after brushing your teeth. Spray the solution into the oral cavity with 3 to 4 pressures of the spray, gargle for about 30 seconds and spit it out. Use OROXID<sup>®</sup> forte regularly, until the situation or elimination of inflammation improves.

OROXID<sup>®</sup> FORTE CONTAINS: deionized water, hydrogen peroxide 30 g/kg, Actipone<sup>®</sup> PX3, flavors, stabilizer.

After activation of the spray the product is recommended to be used within 3 months.

e 100 ml



OROXID<sup>®</sup>  
forte

ORAL HYGIENE  
SPRAY

OROXID<sup>®</sup>  
forte

MUNDHYGIENE  
SPRAY



HEALTHY  
&  
FRESH SMILE



ALCOHOL FREE  
CHLORHEXIDINE FREE



FRISCHES  
&  
GESUNDES LÄCHELN



ALKOHOLFREI  
CHLORHEXIDINEFREI



OROXID<sup>®</sup>  
forte

MUNDHYGIENE  
SPRAY

#### INNOVATIVE HILFE BEI

- Zahnfleisch, Zungen und Schleimhautentzündung
- blutendem und gereiztem Zahnfleisch
- Intensive Mundhygiene (auch bei festen Zahnspangen, Prothesen, Implantaten)
- Verringerung des Zungenbelages
- Verhinderung von Zahnablagerungen
- Verringerung der Zahnverfärbung
- Wiederherstellung des frischen Atems



Vor Gebrauch Beipackzettel lesen



Lösung bei Temperatur von 5 °C bis 25 °C lagern



Lösung vor direktem Licht schützen



Für Kinder unzugänglich aufbewahren



Augenkontakt vermeiden

#### GEBRAUCHSANWEISUNG

OROXID<sup>®</sup> forte ist zwei bis drei Mal pro Tag, vorzugsweise bei und nach dem Zähneputzen, anzuwenden. Die Lösung sollte in die Mundhöhle (3-4 Dosen) gesprüht werden. Mit der Lösung ist ca. 30 Sekunden zu gurgeln und danach auszuspucken. OROXID<sup>®</sup> forte ist regelmäßig bis zur Beseitigung von Entzündungen zu verwenden.

OROXID<sup>®</sup> FORTE BEINHÄLTET: deionisiertes Wasser, Wasserstoffperoxid 30 g/kg, Actipone<sup>®</sup> PX3, Aromastoffe und Stabilisator.

Nach dem Öffnen wird empfohlen, das Produkt innerhalb von drei Monaten zu verbrauchen.

Manufacturer/Hersteller:



ENIKAM d.o.o.  
C. Andreja Bitenca 118  
1000 Ljubljana, Slovenia  
info@enikam.com  
www.oxid.com



# OROXID FORTE ORAL HYGIENE

hydrogen peroxide spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81794-800
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	2.94 mL in 2.94 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>COMMIPHORA MYRRHA STEM BARK</b> (UNII: I4FHO0W8V5)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GINGER</b> (UNII: C5529G5JPQ)	
<b>ECHINACEA PURPUREA</b> (UNII: QI7G114Y98)	
<b>STEVIA EUPATORIA WHOLE</b> (UNII: D0Y0869IHX)	
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	
<b>PEG-40 CASTOR OIL</b> (UNII: 4ERD2076EF)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81794-800-30	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/21/2021	
2	NDC:81794-800-40	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	06/21/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/21/2021	

# OROXID FORTE ORAL HYGIENE

hydrogen peroxide solution

## Product Information



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81794-900	
<b>Route of Administration</b>	ORAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		HYDROGEN PEROXIDE	2.94 mL in 2.94 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
COMMIPHORA MYRRHA STEM BARK (UNII: I4FHO0W8V5)				
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
GINGER (UNII: C5529G5JPQ)				
ECHINACEA PURPUREA (UNII: QI7G114Y98)				
STEVIA EUPATORIA WHOLE (UNII: D0Y0869IHX)				
SPEARMINT (UNII: J7I2T6IV1N)				
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81794-900-70	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2021	
2	NDC:81794-900-60	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2021	
3	NDC:81794-900-50	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2021	
4	NDC:81794-900-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/21/2021	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	06/21/2021		

**Labeler** - Innova Medical Group (117663689)

### Establishment

Name	Address	ID/FEI	Business Operations
Innova Medical Group		117663689	label(81794-800, 81794-900)

## Establishment

Name	Address	ID/FEI	Business Operations
ENIKAM d.o.o.		520197715	manufacture(81794-800, 81794-900)

Revised: 7/2021

Innova Medical Group