CHLORHEXIDINE GLUCONATE, 0.12% ORAL RINSE SOLUTION- chlorhexidine gluconate, 0.12% oral rinse solution solution Bajaj Medical, LLC

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Chlorhexidine Gluconate, 0.12% Oral Rinse Solution BAJAJ MEDICAL, LLC

#### **DESCRIPTION**

0.12% chlorhexidine gluconate (CHG) is an oral rinse containing (1, 1'-hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine gluconate product is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is:

#### CLINICAL PHARMACOLOGY

Chlorhexidine gluconate oral rinse provides antimicrobial activity during oral rinsing. The clinical significance of chlorhexidine gluconate oral rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54–97% through six months use. Use of chlorhexidine gluconate oral rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorhexidine gluconate oral rinse use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

## **Pharmacokinetics**

Pharmacokinetic studies with chlorhexidine gluconate oral rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released into the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 mcg/g in humans 30 minutes after they ingested a 300-mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

#### INDICATION

Chlorhexidine gluconate oral rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine gluconate oral rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS.

#### CONTRAINDICATIONS

Chlorhexidine gluconate oral rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

#### WARNINGS

The effect of chlorhexidine gluconate oral rinse on periodontitis has not been determined. An increase in supragingival calculus was noted in clinical testing in chlorhexidine gluconate oral rinse users compared with control users. It is not known if chlorhexidine gluconate oral rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine. SEE CONTRAINDICATIONS.

## **PRECAUTIONS**

#### **General:**

- 1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with chlorhexidine gluconate oral rinse should not be used as a major indicator of underlying periodontitis.
- 2. Chlorhexidine gluconate oral rinse can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of chlorhexidine gluconate oral rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of chlorhexidine gluconate oral rinse users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of chlorhexidine gluconate oral rinse does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from chlorhexidine gluconate oral rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.

3. Some patients may experience an alteration in taste perception while undergoing treatment with chlorhexidine gluconate oral rinse. Rare instances of permanent taste alteration following chlorhexidine gluconate oral rinse use have been reported via post-marketing product surveillance.

# **Pregnancy: Teratogenic Effects**

Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

# **Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when chlorhexidine gluconate oral rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 ml of chlorhexidine gluconate oral rinse per day.

### Pediatric Use

Clinical effectiveness and safety of chlorhexidine gluconate oral rinse have not been established in children under the age of 18.

# Carcinogenesis, Mutagenesis, and Impairment of Fertility

In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian in vivo mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

### ADVERSE REACTIONS

The most common side effects associated with chlorhexidine gluconate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse. The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1%. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with chlorhexidine gluconate oral rinse are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia. Minor irritation and superficial desquamation of the oral

mucosa have been noted in patients using chlorhexidine gluconate oral rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using chlorhexidine gluconate oral rinse.

#### **OVERDOSAGE**

Ingestion of 1 or 2 ounces of chlorhexidine gluconate oral rinse by a small child ( $\sim$ 10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of chlorhexidine gluconate oral rinse is ingested by a small child or if signs of alcohol intoxication develop.

#### **DOSAGE AND ADMINISTRATION**

Chlorhexidine gluconate oral rinse therapy should be initiated directly following a dental prophylaxis. Patients using chlorhexidine gluconate oral rinse should be reevaluated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 15 ml of undiluted chlorhexidine gluconate oral rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using chlorhexidine gluconate oral rinse. Chlorhexidine gluconate oral rinse is not intended for ingestion and should be expectorated after rinsing.

#### **HOW SUPPLIED**

Chlorhexidine gluconate oral rinse is supplied as a blue liquid in 1-pint (473 ml) amber plastic bottle with child-resistant dispensing closure and 1-pint (473 ml) amber plastic bottle with child-resistant closure, 4-ounce (118 ml) amber plastic bottle with child-resistant closure, 64-ounce (1893 ml) white plastic bottle with foam-lined closure and 15 ml unit-dose cup.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].

Rx Only.

Revised: November 2021

Manufactured by:

Bajaj Medical 415 W Pershing Rd. Chicago, IL 60609 USA

#### WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE

Your dentist has prescribed chlorhexidine gluconate oral rinse to treat your gingivitis, to help reduce the redness and swelling of your gums, and also to help you control any gum bleeding. Use chlorhexidine gluconate oral rinse regularly, as directed by your dentist, in addition to daily brushing. Spit out after use, chlorhexidine gluconate oral rinse should not be swallowed. If you develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset

stomach or diarrhea, seek medical attention immediately. Chlorhexidine gluconate oral rinse should not be used by persons who have a sensitivity to it or its components. Chlorhexidine gluconate oral rinse may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months or more frequently if your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. Chlorhexidine gluconate oral rinse may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- Chlorhexidine gluconate oral rinse may taste bitter to some patients and can affect how food and beverages taste. This will become less noticeable in most cases with continued use of chlorhexidine gluconate oral rinse.
- To avoid taste interference, rinse with chlorhexidine gluconate oral rinse after meals. Do not rinse with water or other mouthwashes immediately after rinsing with chlorhexidine gluconate oral rinse.

If you have any questions or comments about chlorhexidine gluconate oral rinse, contact your dentist, pharmacist, or Bajaj Medical toll free at 1-800-581-2528.

Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].

NDC 61037-469-02 CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Swish 1 tablespoon (15ml) in mouth undiluted for 30 seconds, then **spit out**. Use after breakfast and before bedtime. Or, use as prescribed.

**NOTE:** To minimize medicinal taste, do not rinse with water immediately after use.

**INGREDIENTS:** 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

To open, press down while turning cap. To reseal, turn cap past "clicks" until tightly locked

**Rx Only** 

**KEEP OUT OF REACH OF CHILDREN** 

4 oz. (118 ml)

NDC 61037-469-02

# CHLORHEXIDINE **GLUCONATE 0.12%** ORAL RINSE, USP

**DIRECTIONS FOR USE:** Swish 1 tablespoon (15ml) in mouth undiluted for 30 seconds, then spit out. Use after breakfast and before bedtime. Or, use as prescribed.

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Datalase **Imprint** Area

NDC 61037-469-02

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DIRECTIONS FOR USE: Swish 1 tablespoon (15ml) in mouth undiluted for 30 seconds, then spit out. Use after breakfast and before bedtime. Or, use as prescribed.

for full drug information

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To open, press down while turning cap. To reseal, turn cap past "clicks" until tightly locked



Datalase **Imprint** Area

DESCRIPTION: 0.12% chlorhexidine gluconate (CHG) is an oral rinse containing (1. 11-hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan disostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine gluconate product is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical structure is

Use of chlorheddine gluconate oral rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorheddine gluconate oral rinse use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at baseline.

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INDICATION: Chlorhexidine gluconate oral rinse is indicated for use between dental visits as part of a professional program for the treatment of ginglyitis as characterized by redness and swelling of the ginginae, including ginglyial bleeding upon probing. Chlorhexidine gluconate oral rinse has not been tested among patients with acute necorating ulcerating gingivitis (ANUG). For patients having coexisting ginglyitis and periodontifits, see PRECAUTIONS.

CONTRAINDICATIONS: Chlorhexidine gluconate oral rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula

WARNINGS: The effect of chlorhexidine gluconate oral rinse on periodontitis has not WARMINGS: The effect of chromexional gluconate oral rinse on periodontist has not been determined. An increase in surgranginginal calculus was noted in clinical testing in chlorhexidine gluconate oral rinse use results in an increase in subginginal calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine. SEE CONTRAINDICATIONS.

#### PRECAUTIONS:

PRECACTIONS.

General:

1. For patients having cecisting gingivitis and periodontitis, the presence or absence of gingival inflammation following treatment with chlorhexidine gluconate oral rinse should not be used as a major indicator of underlying periodontitis.

2. Chlorhexidine gluconate oral rinse can cause staining of oral surfaces, such as both surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in tool statinging. In clinical testing, 55% of chlorhexidine gluconate oral rinse users exhibited an measurable increase in facial antient or stain, compared to 35% of control users after six months; 15% of chlorhexidine gluconate oral rinse users developed what was judged to be heavy stain, compared to 1% of control

users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of chlorhexidine gluconate oral rinse does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from chlorhexidine gluconate oral rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these restorations.

Some patients may experience an alteration in taste perception while undergoing treatment with chlorhexidine gluconate oral rinse. Rare instances of permanent taste alteration following chlorhexidine gluconate oral rinse use have been reported via post-marketing product surveillance.

Pregnancy: Teratogenic Effects Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be

used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when chlorhexidine gluconate oral rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 ml of chlorhexidine gluconate oral rinse per day.

Pediatric Use: Clinical effectiveness and safety of chlorhexidine gluconate oral rinse have not been established in children under the age of 18.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian in vivo mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS: The most common side effects associated with chlorhexidine gluconate oral frinses are: 1) an increase in staining of teeth addrer oral surfaces; 2 an increase in calculus formation; and 3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local altery-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse.

The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated tongue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1 %. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with chlorhexidine gluconate oral rinse are stomattis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia.

Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine gluconate oral rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using chlorhexidine gluconate oral rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of chlorhexidine gluconate oral rinse by a small child (~10 kg body weight) might result in gastric distress,

including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of chlorhexidine gluconate oral rinse is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: Chlorhexidine gluconate oral rinse therapy should be initiated directly following a dental prophylaxis. Patients using chlorhexidine gluconate oral rinse should be reevaluated and given a thorough prophylaxis at intervals no longer than six months.

Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usual dosage is 15 ml (1 tablespoon) of undituted othorhexidine gluconate oral rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush teeth, or eat immediately after using chlorhexidine gluconate oral rinse. Chlorhexidine gluconate oral rinse is not intended for ingestion and should be expectorated after rinsing.

HOW SUPPLIED: Chlorhexidine gluconate oral rinse is supplied as a blue liquid in 1-pint (473 ml) amber plastic bottle with child-resistant dispensing closure and 1-pint (473 ml) amber plastic bottle with child-resistant closure, 4-ounce (118 ml) amber plastic bottle with child-resistant closure, 6-d-ounce (1893 ml) white plastic bottle with cham-lined closure and 15 ml unit-dose cup.

STORE at  $20^{\circ}$ C to  $25^{\circ}$ C (68°F to  $77^{\circ}$ F), excursions permitted to  $15^{\circ}$ C to  $30^{\circ}$ C (59°F to  $86^{\circ}$ F) [See USP controlled Room Temperature].

Rx Only.

Revised: May 2022

Manufactured by: Baiai Medical, 415 W Pershing Rd., Chicago, IL 60609 USA

WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE Your dentist has prescribed chlorhexidine gluconate oral rinse to treat your gingivitis, to help reduce the redness and swelling of your gums, and also to help you control any gum bleeding. Use chlorhexidine gluconate oral rinse regularly, as directed by your dentist, in addition to daily brushing. Spit out after use, chlorhexidine gluconate oral rinse should not be swallowed.

If you develop allergic symptoms such as skin rash, itch, generalized swelling, breathing difficulties, light headedness, rapid heart rate, upset stomach or darrhea, seek medical attention immediately. Chlorhexidine gluconate oral rinse should not be used by persons who have a sensitivity to it or its components.

Chlorhexidine gluconate oral rinse may cause some tooth discoloration, or increase in tartar (calculus) formation, particularly in areas where stain and tartar usually form. It is important to see your dentist for removal of any stain or tartar at least every six months or more frequently if

your dentist advises.

- Both stain and tartar can be removed by your dentist or hygienist. Chlorhexidine gluconate oral rinse may cause permanent discoloration of some front-tooth fillings.
- To minimize discoloration, you should brush and floss daily, emphasizing areas which begin to discolor.
- Chlorhexidine gluconate oral rinse may taste bitter to some patients and can affect how food and beverages taste. This will become less noticeable in most cases with continued use of chlorhexidine gluconate oral rinse.
- To avoid taste interference, rinse with chlorhexidine gluconate oral rinse after meals. Do not rinse
  with water or other mouthwashes immediately after rinsing with chlorhexidine gluconate oral
  rinse

If you have any questions or comments about chlorhexidine gluconate oral rinse, contact your dentist, pharmacist, or Bajaj Medical toll free at 1-800-581-2528.

Call your health care provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].

NDC 61037-469-02

# CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Swish 1 tablespoon (15ml) in mouth undiluted for 30 seconds, then **spit out**. Use after breakfast and before bedtime. Or, use as prescribed.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

E Rx Only

KEEP OUT OF REACH OF CHILDREN

4 oz. (118 ml)

### INGREDIENTS:

0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Rlue No. 1

To open, press down while turning cap. To reseal, turn cap past "clicks" until tightly locked



# NDC 61037-469-03 CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Fill cap to the "fill line" (15 ml). Swish in mouth undiluted for 30 seconds, then **spit out**. Use after breakfast and before bedtime. Or, use as prescribed.

**NOTE:** To minimize medicinal taste, do not rinse with water immediately after use.

**INGREDIENTS:** 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

To Open: Squeeze smooth areas near bottom of cap and turn. To Close: Turn cap until it locks.

## Rx Only

#### **KEEP OUT OF REACH OF CHILDREN**

## 1 Pint (473 ml)

# Dispense in bottle provided or amber glass

NDC 61037-469-03

CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

DIRECTIONS FOR USE: Fill cap to the "fill line" (15 ml). Swish in mouth undiluted for seconds, then soft out. Use after breakfast and before bedtime. Or, use as prescribed NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE WHAT TO EXPECT WHERE USING CHUCORHEATIONE CLUCONATE ORAL RINES.

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advise about gide effects. You may report effects by FBA at 1-900-FBA-1088.

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areas near bottom of cap and turn. To Close: Turn cap until it locks.

RX Only KEEP OUT OF REACH OF CHILDREN

To Open: Squeeze smooth

1 Pint (473 ml)

*Imprint* 

Area

#### NDC 61037-469-03

#### CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

DIRECTIONS FOR USE: Fill cap to the "fill line" (15 ml). Swish in mouth undiluted for 30 seconds, then spit out. Use after breakfast and before bedtime. Or, use as prescribed.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

KEEP OUT OF REACH OF CHILDREN

1 Pint (473 ml)

Lift here for full drug labeling information

Dispense in bottle as provided or amber glass

To Open: Squeeze smooth areas near bottom of cap and turn. To Close: Turn cap until it locks.

RX Only KEEP OUT OF REACH OF CHILDREN

1 Pint (473 ml)



*Imprint* Area

DESCRIPTION: 0.12% chlorhexidine gluconate (CHG) is an oral rinse containing (1, 1'-hexamethylene bis [5-(p-chlorophenyl) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Sorbitan disostearate, havor, sodium saccharin, and FD&C Blue No. 1.

Chlorhexidine gluconate product is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical



CLINICAL PHARMACOLOGY: Chlorhexidine gluconate oral rinse provides antimicrobial activity during oral rinsing. The clinical significance of chlorhexidine gluconate oral rinse's antimicrobial activities is not clear, Microbiological sampling of glucorate oral inise s'animinotoria accivirses in olici animico in mise s'animino de la plaque has shorn a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-97% through six months use. Use of chlorhexidine glucorate oral rinse in a six month clinical study did not result in any significant changes in special resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorhexidine gluconate oral rinse use was discontinued, the number of bacteria in plaque had returned to baseline evels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at

Pharmacokinetics: Pharmacokinetic studies with chlorhexidine gluconate oral rinse Prantinconneutes: Initiation and initiation and initiation and initiation approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following initiation. This retained drug is slowly released into the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate treached a peak of 0.206 mog/gi in humans 30 minutes after they ingested a 300-mg dose of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the feces (~90%). Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATION: Chlorhexidine gluconate oral rinse is indicated for use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine gluconate oral rinse has not been tested among patients with act necrotizing uscerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS. CONTRAINDICATIONS: Chlorhexidine gluconate oral rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate o other formula ingredients.

WARNINGS: The effect of chlorhexidine gluconate oral rinse on periodontitis WAMNINGS. The elect of commeasuring uncommeasuring uncommeasure was most one personations has not been determined. An increase in supragingival calculus was noted in clinical testing in chlorhexidine gluconate oral rinse users compared with control users. It is not known if chlorhexidine gluconate oral rinse user scutts in an increase in subglingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine. reported during postmarke SEE CONTRAINDICATIONS.

#### PRECAUTIONS:

- General:
  1. For patients having coexisting gingivitis and periodontitis, the presence or absence
- 1. For placetist lawing obecasting unjuries and periodiusts, tier presence in assence of gingvisi Inflammation following treatment with chlorhexidine gluconate oral rinse should not be used as a major indicator of underlying periodiothists. Chlorhexidine gluconate oral rinse can cause staining of oral surfaces, such as both surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining, in clinical testing, 56% of chlorhexidine gluconate oral rinse users exhibited a measurable increase in facial arterior stain, compared to 35% of control users effect in combise, 15% of anterior stain, compared to 35% of control users after six months; 15% of ametino stain, compared to 35% of control users after six months; 15% of technological collaboration and the subset developed what was judged to be heavy stain, compared to 19% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Stain resulting from use of chiorhexidine glucorate or affines does not adversely affect health of the gingivae or other oral tissues. Stain can be removed from most tooth surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from chorevaidine gluconate oral rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these
- 3. Some patients may experience an alteration in taste perception while undergoing treatment with chlorhexidine gluconate oral rinse. Rare instances of permanent ta alteration following chlorhexidine gluconate oral rinse use have been reported via post-marketing product surveillance.

Pregnancy: Teratogenic Effects Reproduction studies have been performe rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk Because many drugs are excreted in human milk, caution should be exercised when chlorhexidine gluconate oral rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which ould result from a person's ingesting 30 ml (2 capfuls) of chlorhexidine gluconate

Pediatric Use: Clinical effectiveness and safety of chlorhexidine gluconate oral rinse have not been established in children under the age of 18.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In a drinking water Carcinogenesis, Mutagenesis, and impairment of Fertility: In a drinking water study in rats, carinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammallar in vivo mutagenesis studies with chiorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day, respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS: The most common side effects ADVERSE REACTIONS: The most common side effects associated with chlorhexidine gluconate oral trinses are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in eaterlus formation; and 3) an alteration in taste perception; see WARNINGS and PRECUTIONS. Oral Intration and local allergy—bpe symptoms have been spontaneously reported as side effects associated with use of chlorhexidine gluconate rinse. The following oral mucosal side effects were reported during placebo-controller adult clinical trials: aphthous ulcer, grossly obvious ginglyttis, trauma, ulceration, erythema, desquamation, coated longue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1%. Among post marketing reports, the most frequently reported oral mucosal symptoms associated with chlorhexidine gluconate oral rinse are stomatitis, ginglyttis, glosstifis, ulcer, dy mouth, gluconate oral rinse are stomatitis, gingivitis, glossitis, ulcer, dry mouth, hypesthesia, glossal edema, and paresthesia. Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine

gluconate oral rinse. There have been cases of parotid gland swelling and NDC 61037-469-03 OVERDOSAGE: Ingestion of 1 or 2 ounces of chlorhexidine gluconate oral rinse by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP sought if more than 4 ounces of chlorhexidine gluconate oral rinse is ingested by a small child or if signs of alcohol intoxication develop. DIRECTIONS FOR USE: Fill cap to the "fill line" (15 ml). DOSAGE AND ADMINISTRATION: Chlorhexidine ate oral rinse therapy should be initiated directly following a dental Swish in mouth undiluted for 30 seconds, then spit out. Use prophylaxis. Patients using chlorhexidine gluconate oral rinse should be after breakfast and before bedtime. Or, use as prescribed. eevaluated and given a thorough prophylaxis at intervals no longer than six reevaluated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning an evening after toothbrushing, Usual dosage is 15 ml (marked in cap) of undiluted chiohreakidine gloconate oral rinse. Patients should be instructed to not rinse with water, or other mouthwashes, brush beth, or eat immediately after using chiomediade gloconate oral rinse. Chiomekudine gluconate oral rinse is not intended for ingestion and should be expectorated after rinsing. NOTE: To minimize medicinal taste, do not rinse with water immediately after use. INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan HOW SUPPLIED: Chlorhexidine gluconate oral rinse is supplied as a diisostearate, flavor, sodium saccharin and FD&C Blue No. 1. blue liquid in 1-pint (473 ml) amber plastic bottle with child-resistant dispensing closure and 1-pint (473 ml) amber plastic bottle with child-resistant closure, 4-ounce (118 ml) amber plastic bottle with child-resistant closure, 64-ounce (1893 ml) white plastic bottle with foam-lined closure and 15 ml unit-dose cup. KEEP OUT OF REACH OF CHILDREN STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature]. 1 Pint (473 ml) Revised: May 2022 Manufactured by: 415 W Pershing Rd Chicago, IL 60609 USA Dispense in bottle as provided or amber glass

# NDC 61037-469-05 CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Dispense 15 ml of the oral rinse into a suitable patient cup. Swish in mouth undiluted for 30 seconds, then **spit out**.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

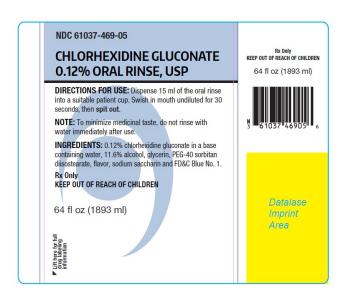
**INGREDIENTS:** 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

# **Rx Only**

#### **KEEP OUT OF REACH OF CHILDREN**

### 64 fl oz (1893 ml)





DESCRIPTION: 0.12% chlorhexidine gluconate (CHG) is an oral rinse containing (1, 11-hexametrylene bis [5-(p-chioropheny) biguanide] di-D-gluconate) in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine gluconate product is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical

CLINICAL PHARMACOLOGY: Chlorhexidine gluconate oral rinse rounder an inservoide activity during oral rinsing. The clinical significance of chlorhexidine gluconate oral rinse's antimicrobial activity during oral rinsing. The clinical significance of chlorhexidine gluconate oral rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 4-97% through six months use. Use of chlorhexidine gluconate oral rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorhexidine gluconate oral rinse use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at

Pharmacokinetics: Pharmacokinetic studies with chlorhexidine gluconate oral rinse Pharmacokinetics: Pharmacokinetic studies with follorhavidine gluconate oral rinse indicate approximately 30% of the active ingredient, chlorhavidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released into the oral fluids. Studies conducted on human subjects and animatels demonstrate chlorhavidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhavidine gluconate is only absorbed from the gastrointestinal tract. The mean plasma level of chlorhavidine gluconate reached a peak of 0.206 mcg/g in humans 30 minutles after they ingested a 300-mg does of the drug. Detectable levels of chlorhavidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhavidine gluconate occurred primarily through the feeces (~90%), Less than 1% of the chlorhavidine gluconate ingested by these subjects was excreted in the urine.

INDICATION: Chlorhexidine gluconate oral rinse is indicated for use between INDICATION. Underskinding bloomer and miss is indicated or tax between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine gluconate oral rinse has not been tested among patients with acute necrotizing ulcerative gingivitis (ANUG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS. CONTRAINDICATIONS: Chlorhexidine gluconate oral rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

WARNINGS: The effect of chlorhexidine gluconate oral rinse on periodontitis as not been determined. An increase in supragingival calculus was noted in clinical sting in chlorhexidine gluconate oral rinse users compared with control users. It is not known if chlorhexidine gluconate oral rinse use results in an increase in subgingival calculus. Calculus deposits should be removed by a dental prophylaxis at intervals not greater than six months. Anaphylaxis, as well as serious allergic reactions, have been reported during postmarketing use with dental products containing chlorhexidine. SEE CONTRAINDICATIONS

#### PRECAUTIONS:

- General:
  1. For patients having coexisting gingivitis and periodontitis, the presence or absence of gingival inflammation follow ng treatment with chlorhexidine gluconate oral rinse
- or grigival intammation tollowing treatment with chlorhexidine gluconate oral rinse should not be used as a major indicator of underlying periodontitis.

  2. Chlorhexidine gluconate oral rinse can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of chlorhexidine gluconate oral rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of chlorhexidine gluconate oral rinse users designed what we intend to be home. amenor stam, compared to 35% of control users after six months; 15% of chlorhexiding gluconate oral rinse users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of unremoved plaque. Sta resulting from use of chlorhexidine gluconate oral rinse does not adversely affect health of the gingiyae or other oral tissues. Stain can be removed from most tooth ineatin or the glingived or other fair assesses. Saint car be tembered from insist own surfaces by conventional professional prophylactic techniques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from chlorhecidine glucorate oral rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these
- uerical propripatos and of rare occasions may necessitate repracement of these restorations.

  3. Some patients may experience an alteration in taste perception while undergoing treatment with chlorhexidine gluconate oral rinse. Pare instances of permanent taste alteration following chlorhexidine gluconate oral rinse use have been reported via post-marketing product surveillance.

Pregnancy: Teratogenic Effects Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. ver, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when chlorhexidine gluconate oral rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 ml of chlorhexidine gluconate oral rinse

Pediatric Use: Clinical effectiveness and safety of chlorhexidine gluconate oral rinse have not been established in children under the age of 18.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mamalian in vivo mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day. Seponderics test were 1000 mg/kg/day to be evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS: The most common side effects ADVEHSE HEACTIONS: The most common side effects associated with tolhrexidine gluconate oral insess are: 1) an increase in staining of teeth and other oral surfaces; 2) an increase in calculus formation; and 3) an attentain in tacte perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allergy-type symptoms have been spontaneously reported as side effects associated with use of hiothexidine gluconate rines. The following ural mucosal side effects were reported during plazebo-controlled adult clinical trials: aphthous ulcer, grossly obvious glingivitis, trauma, ulceration, erythema, desquamation, coated forgue, keratinization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1% Among opts marketing reports, the most frequentity reported and mucosal symptoms associated with hothexidine book frequently reported oral mucosal symptoms associated with chlorheaddine gluconate oral rinse are stomatifis, gingwits, glossitis, ulcer, dry mouth, hypesthesia, glossal edma, and praersthesia. Minor rintation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine

gluconate oral rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using chlorhexidine gluconate oral rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of chlorhexidine gluconate oral rinse by a small child (~10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of chlorhexidine gluconate oral rinse is ingested by a small child or if signs of alcohol intoxication develop.

DOSAGE AND ADMINISTRATION: Chlorhexiding DUSAGE AND ADMINIST HATION: chromextaine gluconate oral rinse therapy should be initiated directly following a dental prophylaxis. Patients using chlorhexidine gluconate oral rinse should be revealuated and given a thorough prophylaxis at intervals no longer than six months. Recommended use is twice daily oral rinsing for 30 seconds, morning and evening after toothbrushing. Usad dosage is 15 m of unditude chrothexidine gluconate oral rinse, Patients should be instructed to not rinse with water, or other special and the state of a little state of the state of t

HOW SUPPLIED: Chlorhexidine gluconate oral rinse is supplied as a blue liquid in 1-pint (473 ml) amber plastic bottle with child-resistant dispensing closure and 1-pint (473 ml) amber plastic bottle with child-resistant closure, 4-ounce (118 ml) amber plastic bottle with child-resistant closure, 6-ounce (1893 ml) white plastic bottle with foam-lined closure and 15 ml unit-dose cup.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].

Rx Only.

Revised: May 2022

Manufactured by: Bajaj Medical 415 W Pershing Rd Chicago, IL 60609 USA NDC 61037-469-05

# CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Dispense 15 ml of the oral rinse into a suitable patient cup. Swish in mouth undiluted for 30 seconds, then spit out.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

KEEP OUT OF REACH OF CHILDREN

64 fl oz (1893 ml)

# NDC 61037-469-07 CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Swish in mouth undiluted for 30 seconds, then **spit out.** Use after breakfast and before bedtime. Or, use as prescribed.

**NOTE:** To minimize medicinal taste, do not rinse with water immediately after use.

**INGREDIENTS:** 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

Rx Only

KEEP OUT OF REACH OF CHILDREN

100 Unit Dose Cups

# (Each Cup Delivers 15 mL)

# NDC 61037-469-07 CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Swish in mouth undituted for 30 seconds, then **spit out**. Use at breakfast and before bedtime. Or, use as prescribed.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use. INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

WHAT TO EXPECT WIREN USING CHAPMEN USING ELOCOMATE DRAIL RINSE
Your dentist has prescribed charberatine glocomate for an interest to the styp us optional style and the state of the style and problems, to help reduce the reclaims and swelling of your dentist only believe to the style of problems, and also be in breatly one control and many thereoff the state of the st WHAT TO EXPECT WHEN USING CHLORHEXIDINE GLUCONATE ORAL RINSE

RX Only KEEP OUT OF REACH OF CHILDREN

100 Unit Dose Cups (Each Cup Delivers 15 mL)



Datalase g Area

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NDC 61037-469-07

#### **CHLORHEXIDINE GLUCONATE** 0.12% ORAL RINSE, USP

DIRECTIONS FOR USE: Swish in mouth undiluted for 30 seconds, then **spit out**. Use after breakfast and before bedtime. Or, use as prescribed.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

Rx Only KEEP OUT OF REACH OF CHILDREN

100 Unit Dose Cups (Each Cup Delivers 15 mL)

Rx Only Keep out of reach of Children

100 Unit Dose Cups (Each Cup Delivers 15 mL)



Datalase *Imprint* Area

gluconate oral rinse. There have been cases of parotid gland swelling and inflammation of the salivary glands (sialadenitis) reported in patients using chlorhexidine gluconate oral rinse.

OVERDOSAGE: Ingestion of 1 or 2 ounces of chlorhexidine gluconate oral rinse by a small child (-10 kg body weight) might result in gastric distress, including nausea, or signs of alcohol intoxication. Medical attention should be sought if more than 4 ounces of chlorhexidine gluconate oral rinse is ingested by a small child or if signs of alcohol intoxication develop.

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HOW SUPPLIED: Chlorhexidine gluconate oral rinse is supplied as a blue liquid in 1-pirit (473 ml) amber plastic bottle with child-resistant dispensing closure and 1-pirit (473 ml) amber plastic bottle with child-resistant closure, 4-ounce (118 ml) amber plastic bottle with child-resistant closure, 6-ounce (1893 ml) white plastic bottle with foam-lined closure and 15 ml unit-dose cup.

STORE at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled Room Temperature].

Rx Only.

Revised: May 2022

Manufactured by: Bajaj Medical 415 W Pershing Rd. Chicago, IL 60609 USA NDC 61037-469-07

# CHLORHEXIDINE GLUCONATE 0.12% ORAL RINSE, USP

**DIRECTIONS FOR USE:** Swish in mouth undiluted for 30 seconds, then spit out. Use after breakfast and before bedtime. Or, use as prescribed.

NOTE: To minimize medicinal taste, do not rinse with water immediately after use.

INGREDIENTS: 0.12% chlorhexidine gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No. 1.

Rx Only KEEP OUT OF REACH OF CHILDREN

100 Unit Dose Cups (Each Cup Delivers 15 mL)

DESCRIPTION: 0.12% chlorhexidine gluconate (CHG) is an oral rinse containing (1, 1\*-hexametriylene bis [5-(n-chiorpheny) biguanide] di-D-gluconate) in a base containing water, 11.6% alcoho, glycerin, PEG-40 sorbitan disostearate, flavor, sodium saccharin, and FD&C Blue No. 1. Chlorhexidine gluconate product is a near-neutral solution (pH range 5-7). Chlorhexidine gluconate is a salt of chlorhexidine and gluconic acid. Its chemical

CLINICAL PHARMACOLOGY: Chlorhexidine gluconate oral rinse provides antimicrobial activity during oral rinsing. The clinical significance of chlorheavidine gluconate oral rinse's antimicrobial activities is not clear. Microbiological sampling of plaque has shown a general reduction of counts of certain assayed bacteria, both aerobic and anaerobic, ranging from 54-79% through is months use. Use of chlorheavidine gluconate oral rinse in a six month clinical study did not result in any significant changes in bacterial resistance, overgrowth of potentially opportunistic organisms or other adverse changes in the oral microbial ecosystem. Three months after chlorhexidine gluconate oral rinse use was discontinued, the number of bacteria in plaque had returned to baseline levels and resistance of plaque bacteria to chlorhexidine gluconate was equal to that at

Pharmacokinetics: Pharmacokinetic studies with chlorhexidine gluconate oral rinse Pharmacokinetics: Pharmacokinetic studies with chlorhexidine gluconate oral rinse indicate approximately 30% of the active ingredient, chlorhexidine gluconate, is retained in the oral cavity following rinsing. This retained drug is slowly released into the oral fluids. Studies conducted on human subjects and animals demonstrate chlorhexidine gluconate is poorly absorbed from the gastrointestinal tract. The mean plasma level of chlorhexidine gluconate reached a peak of 0.206 mog in humans 30 minutes after they ingested a 300-mg does of the drug. Detectable levels of chlorhexidine gluconate were not present in the plasma of these subjects 12 hours after the compound was administered. Excretion of chlorhexidine gluconate occurred primarily through the fees 4-90%, Less than 1% of the chlorhexidine gluconate ingested by these subjects was excreted in the urine.

INDICATION: Chlorhexidine gluconate oral rinse is indicated for use between INDICATION. Underskinding quocinate or an interest indicated or use between dental visits as part of a professional program for the treatment of gingivitis as characterized by redness and swelling of the gingivae, including gingival bleeding upon probing. Chlorhexidine gluconate or al rinse has not been tested among patients with acute necrotizing ulearative gingivitis (ANJG). For patients having coexisting gingivitis and periodontitis, see PRECAUTIONS. CONTRAINDICATIONS: Chlorhexidine gluconate oral rinse should not be used by persons who are known to be hypersensitive to chlorhexidine gluconate or other formula ingredients.

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#### PRECAUTIONS:

- General:
  1. For patients having coexisting gingivitis and periodontitis, the presence or absence
- 1. For jaxenis liaming ceessing gringings and periodisting, the presence of adjusted inflammation following treatment with chlorhexidine gluconate oral rinse should not be used as a major indicator of underlying periodontitis.
  2. Chlorhexidine gluconate oral rinse can cause staining of oral surfaces, such as tooth surfaces, restorations, and the dorsum of the tongue. Not all patients will experience a visually significant increase in toothstaining. In clinical testing, 56% of chlorhexidine gluconate oral rinse users exhibited a measurable increase in facial anterior stain, compared to 35% of control users after six months; 15% of achilohomadine glouconate oral trinse users developed what was judged to be heavy stain, compared to 1% of control users after six months. Stain will be more pronounced in patients who have heavier accumulations of une health of the gingivae or other oral tissues. Stain can be removed from most tooth neatin or the gingified or other fair assess. Saint can be reinvect from institutions surfaces by conventional professional prophylactic bechiques. Additional time may be required to complete the prophylaxis. Discretion should be used when prescribing to patients with anterior facial restorations with rough surfaces or margins. If natural stain cannot be removed from these surfaces by a dental prophylaxis, patients should be excluded from chlorhecidine glucorate oral rinse treatment if permanent discoloration is unacceptable. Stain in these areas may be difficult to remove by dental prophylaxis and on rare occasions may necessitate replacement of these
- restorations.

  3. Some patients may experience an alteration in taste perception while undergoing treatment with chlorhexidine gluconate oral rinse. Rare instances of permanent taste alteration following chlorhexidine gluconate oral rinse use have been reported via post-marketing product surveillance.

Pregnancy: Teratogenic Effects Reproduction studies have been performed in rats and rabbits at chlorhexidine gluconate doses up to 300 mg/kg/day and 40 mg/kg/day, respectively, and have not revealed evidence of harm to fetus. However, adequate and well-controlled studies in pregnant women have not been done. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk Norsing woulders: it is not known whether his budge is exceeded in human milk, caution should be because many drugs are excreted in human milk, caution should be marcrised when chlorhexidine gluconate oral rinse is administered to nursing women. In parturition and lactation studies with rats, no evidence of impaired parturition or of toxic effects to suckling pups was observed when chlorhexidine gluconate was administered to dams at doses that were over 100 times greater than that which would result from a person's ingesting 30 ml of chlorhexidine gluconate oral rinse

Pediatric Use: Clinical effectiveness and safety of chlorhexidine gluconate oral rinse have not been established in children under the age of 18

Carcinogenesis, Mutagenesis, and Impairment of Fertility: In a drinking water study in rats, carcinogenic effects were not observed at doses up to 38 mg/kg/day. Mutagenic effects were not observed in two mammalian in vivo mutagenesis studies with chlorhexidine gluconate. The highest doses of chlorhexidine used in a mouse dominant-lethal assay and a hamster cytogenetics test were 1000 mg/kg/day and 250 mg/kg/day; respectively. No evidence of impaired fertility was observed in rats at doses up to 100 mg/kg/day.

ADVERSE REACTIONS: The most common side effects ADVERSE REACTIONS: The most common side effects associated with chlorhexidine glucorate oral rinses are: 1) an increase in staining of teeth and other oral surfaces; 2 an increase in calculus formation; and 3) an alteration in taste perception; see WARNINGS and PRECAUTIONS. Oral irritation and local allery-type symptoms have been spontaneously reported as side effects associated with use of chlorhexidine glucorate rinse. The following oral mucosal side effects were reported during placebo-controlled adult clinical trials: aphthous ulcer, grossly obvious gingivitis, trauma, ulceration, erythema, desquamation, coated torgue, kerathrization, geographic tongue, mucocele, and short frenum. Each occurred at a frequency of less than 1% Annong post marketing reports, the most frequently reported oral mucosal symptoms associated with chlorhexidine glucorate or all rinse are shomatifis, gingivitis, glossisii, ulcer, dry mouth, hypesthesia, glossal edema, and peresthesia. Minor irritation and superficial desquamation of the oral mucosa have been noted in patients using chlorhexidine

# **CHLORHEXIDINE GLUCONATE, 0.12% ORAL RINSE SOLUTION**

chlorhexidine gluconate, 0.12% oral rinse solution solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61037-469
Route of Administration	DENTAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1.2 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GLYCERIN (UNII: PDC6A3C0OX)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7I1G)		
ALCOHOL (UNII: 3K9958V90M)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics		
Color	blue	Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

Packaging				
#	Item Code	Package Description  Marketing Start Marketing B Date Date		Marketing End Date
1	NDC:61037- 469-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2021	
2	NDC:61037- 469-03	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2021	
3	NDC:61037- 469-05	1893 mL in 1 JUG; Type 0: Not a Combination Product	11/17/2021	
4	NDC:61037- 469-07	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	11/17/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA075561	11/17/2021		

# Labeler - Bajaj Medical, LLC (078774921)

# Registrant - Bajaj Medical, LLC (078774921)

Establishment			
Name	Address	·	Business Operations
Bajaj Medical, LLC		078774921	analysis(61037-469), label(61037-469), manufacture(61037-469), pack(61037-469)

Revised: 1/2024 Bajaj Medical, LLC