

## **HYDROGEMTOOTHPASTE- calcium hydrogen phosphate hydrate paste, dentifrice**

**H2 biohealthcare Co.,Ltd**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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calcium hydrogen phosphate hydrate

- Prevention of cavities, removal of bad breath, prevention of gum disease
- Prevention of gingivitis and periodontitis

Keep out of reach of children

apply appropriate amount of the tooth paste on the tooth brush and brush the teeth

For dental use only

When using this product

- top use and ask a dentist if oral irritation or tooth sensitivity occurs
- Be careful not to swallow and rinse your mouth thoroughly after use.
- If any abnormality occurs while using toothpaste, such as damage to the gums or inside of the mouth, stop using it immediately and consult a dentist.

L-menthol, glycerin, saccharin sodium hydrate, spearmint oil, xylitol, purified water, sodium carboxymethyl cellulose, cocamidopropyl betaine, propolis

For dental use only

## HYDRO-GEM

### Drug Facts

#### Active Ingredients

calcium hydrogen phosphate hydrate ----- Purpose  
anticaries

#### Uses

- Prevention of cavities, removal of bad breath, prevention of gum disease
- Prevention of gingivitis and periodontitis

#### Warning

For dental use only

#### When using this product

- top use and ask a dentist if oral irritation or tooth sensitivity occurs
- Be careful not to swallow and rinse your mouth thoroughly after use.
- If any abnormality occurs while using toothpaste, such as damage to the gums or inside of the mouth, stop using it immediately and consult a dentist.

#### Directions

- Apply an appropriate amount to a toothbrush and brush your teeth.

#### Other Information

- read the directions and warnings before use
- avoid freezing and excessive heat above 40 degree C (104 degree F)

#### Inactive Ingredients

L-menthol, glycerin, saccharin sodium hydrate, spearmint oil, xylitol, purified water, sodium carboxymethyl cellulose, cocamidopropyl betaine, propolis

[MANUFACTURER] H2 biohealthcare Co.,Ltd.

## HYDROGEMTOOTHPASTE

calcium hydrogen phosphate hydrate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83811-0001
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J) (CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS - UNII:L11K75P92J)	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	2.14 g in 100 g
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## Inactive Ingredients

Ingredient Name	Strength
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
<b>1</b>	NDC:83811-0001-1	150 g in 1 TUBE; Type 0: Not a Combination Product	11/20/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/20/2023	

**Labeler** - H2 biohealthcare Co.,Ltd (695269509)

**Registrant** - H2 biohealthcare Co.,Ltd (695269509)

## Establishment

Name	Address	ID/FEI	Business Operations
H2 biohealthcare Co.,Ltd		695269509	manufacture(83811-0001)

Revised: 11/2023

H2 biohealthcare Co.,Ltd