

OROXID SENSITIV- hydrogen peroxide solution

OROXID SENSITIV- hydrogen peroxide spray

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.

Instruction For use

Use OROXID® sensitiv two to three times a day preferably during or after brushing your teeth. Pour approximately 20 ml of liquid (content of two cups) into a glass, gargle for about 30 seconds and spit it out afterwards. OROXID® sensitiv is suitable for a long-term use.

OTC Active Ingredient

hydrogen peroxide

Storage and handling



OROXID®
sensitiv

ORAL HYGIENE
SPRAY

INNOVATIVE HELP WITH

- Inflammation of the oral cavity
- Maintenance of oral hygiene
- Hygiene of orthodontic appliances, braces, dentures, implants
- Prevention of dental plaque
- Reduction of tooth stains
- Restoration of fresh breath

SUITABLE FOR

- All generations
- Sensitive mucous membranes
- Long-term use



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

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OROXID® SENSITIV CONTAINS: deionized water, hydrogen peroxide 15 g/kg, Actipone® PX3, flavors, stabilizer.

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

100 ml



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Manufacturer

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CE 1304

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Inactive Ingredient

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Dosage and administration



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Warning



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Keep reach of Children

Keep away from Children

Purpose



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 SPRAY

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sensitiv

MUNDHYGIENE
 SPRAY

INNOVATIVE HILFE BEI

- Entzündung der Mundhöhle
- Intensive Mundhygiene
- Hygiene der festen Zahnsparagen, Prothesen, Implantaten
- Verringerung der Zahnverfärbung
- Verhinderung von Zahnablagerungen
- Wiederherstellung des frischen Atems

GEEIGNET FÜR

- alle Generationen
- empfindliche Mundschleimhäute
- längerfristige Anwendung

- 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[®] sensitiv 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[®] sensitiv ist geeignet für die längerfristige Anwendung.

OROXID[®] SENSITIV BEINHALTET: deionisiertes Wasser, Wasserstoffperoxid 15 g/kg, Actipone[®] PX3, Aromastoffe und Stabilisator.

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

Manufacturer/Hersteller:

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1304

HEALTHY & FRESH SMILE



ALCOHOL FREE
 CHLORHEXIDINE FREE

FRISCHES & GESUNDES LÄCHELN



ALKOHOLFREI
 CHLORHEXIDINEFREI



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OROXID SENSITIV
hydrogen peroxide solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81794-600
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	1.5 mL in 1.5 mL

Inactive Ingredients

Ingredient Name	Strength
GINGER (UNII: C5529G5JPQ)	
ECHINACEA PURPUREA WHOLE (UNII: QI7G114Y98)	
COMMIPHORA MYRRHA STEM BARK (UNII: I4FHO0W8V5)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
SPEARMINT (UNII: J7I2T6IV1N)	
WATER (UNII: 059QF0KOOR)	
STEVIA EUPATORIA WHOLE (UNII: D0Y0869IHX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81794-600-70	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2021	
2	NDC:81794-600-50	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2021	
3	NDC:81794-600-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2021	
4	NDC:81794-600-60	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/12/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/12/2021	

OROXID SENSITIV

hydrogen peroxide spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81794-700
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Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	1.5 mL in 1.5 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	SPEARMINT (UNII: J7I2T6IV1N)			
	GINGER (UNII: C5529G5JPQ)			
	WATER (UNII: 059QF0KOOR)			
	PEG-40 CASTOR OIL (UNII: 4ERD2076EF)			
	ECHINACEA PURPUREA WHOLE (UNII: QI7G114Y98)			
	COMMIPHORA MYRRHA STEM BARK (UNII: I4FHO0W8V5)			
	STEVIA EUPATORIA WHOLE (UNII: D0Y0869IHX)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81794-700-30	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/12/2021	
2	NDC:81794-700-40	50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/12/2021	
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	OTC monograph not final	part333A	07/12/2021	

Labeler - Innova Medical Group (117663689)

Establishment

Name	Address	ID/FEI	Business Operations
Innova Medical Group		117663689	label(81794-600, 81794-700)

Establishment

Name	Address	ID/FEI	Business Operations
ENIKAM d.o.o.		520197715	manufacture(81794-600, 81794-700)