
	TF TEETHING GEL	Rev. n°01	15.10.2022
Medical Device Name: TEETHING GEL		MD N° 04 of 2017	
Author: Farmaceutici Procemsa S.p.A.SB			
ANNEX 01 SECTION 02		REV 01 of 15.10.2022	

## TEething GEL

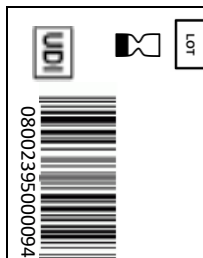
 <p>Prodotti Chimici e Medicinali Società Anonima</p>	TF TEETHING GEL	Rev. n°01	15.10.2022
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\*\*\* the REF code can correspond to the catalogue code of the manufacturer's finished product








(01) 08002395000094  
(17) Expiration date  
(10) Lot/Batch n°




The graphic representation of the UDI-DI code generated and inserted by the Manufacturer on the carton box, will be made according to one of the following two GS1 standards:  
- GS1-128 Not concatenated (UDI-DI only) (Option 1)  
- QR Code (UDI-DI+UDI-PI) with HRI (Option 2)

## BOX

External dimension:  
40,5x30,5x146,5 mm

 <b>ATTENTION:</b> before use carefully read the internal warnings and operating instructions supplied in the inner leaflet.		
Distributor  Farmaceutici Procemsa S.p.A. SB Via Mentana 10 – 10042 Nichelino	14353218 (Procemsa Artwork code)	
<b>REF</b> 1130862 (Catalogue code)***		
<p><b>INDICATION:</b> TEething GEL is indicated to treat the symptoms of teething in infants, especially to decrease the pain sensation and the reddening of the interested area. TEething GEL does not contain sugar, honey, aspartame, saccharin or other artificial sweeteners, flavors, alcohol, local anesthetics, parabens.</p> <p><b>COMPOSITION:</b> Xylitol, aqua, glycerin, Rosa damascena flower extract, xanthan gum, hyaluronic acid (0,2%), potassium sorbate (0,1%) pectin, sodium benzoate (0,1%), citric acid, Malva sylvestris extract (0,05%), Chamomile recutita flower extract (0,05%), Aloe barbadensis leaf extract (0,05%).</p>		
<p><b>USE AND DOSAGE:</b> Apply enough product to cover the interested area and gently massage the gums. Use preferably after meals and before sleeping in order to help the formation of the film and prolong the duration of the relief. Use 3- 5 times per day, as needed. Recap after each application. Is not recommended the use of the product for children under 6 months.</p> <p><b>STORE AND CONSERVATION:</b> Store below 25 °C. The expiry date refers to the product intact and properly stored. Do not use beyond the expiration date on the package. Use within 30 days after the first opening. The residue or expired product can be disposed as normal household waste. <b>Keep the product out of reach and view of children.</b></p>		
<div style="text-align: center;"> <h1>TEething GEL</h1>  <h2>MEDICAL DEVICE</h2> <p>Tube of 15 ml</p>  </div>		

**TEething GEL**  
**MEDICAL DEVICE**  
 Tube of 15 ml

 <small>Prodotti Chimici e Medicinali Società Anonima</small>	<b>TF TEETHING GEL</b>	<b>Rev. n°01</b>	<b>15.10.2022</b>
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<b>ANNEX 01 SECTION 02</b>		<b>REV 01 of 15.10.2022</b>	

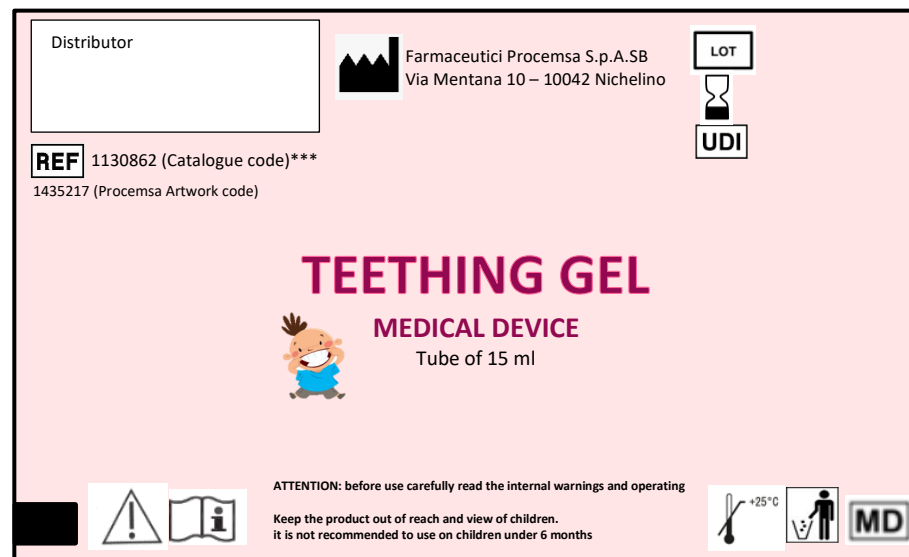
## TEETHING GEL

ARTWORK TUBE  
Dimension: Ø19x88 mm

Welding and eye-mark area 77 mm

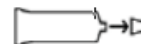
No printable area 3mm


62 mm



The product sales unit consists of a case, tube and leaflet. Should it be necessary to implement the UDI code also on the tube (which cannot be sold individually), the manufacturer will, space permitting, place the UDI-DI code for this device next to the UDI logo. The graphic representation of the UDI-DI code generated and inserted by the Manufacturer on the carton box, will be made according to one of the GS1 standards. The code will be placed near the UDI symbol.

88 mm




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## TEething GEL

LEAFLET  
Dimension: 120X150 mm

FRONT SIDE

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## TEETHING GEL

### MEDICAL DEVICE

Tube of 15 ml

#### TEETHING GEL:

TEETHING GEL is a muco-adhesive gel that quickly makes a film on the gum that is able to relieve pain and discomfort due to teething in children. The formula contains hyaluronic acid and pectin, ingredients that are able to form the film on the interested parts. It also contains high quality natural vegetal extracts (Rosa Damascena petals, Chamomile, Aloe and Mallow) that have lenitive and refreshing action.

TEETHING GEL does not contain sugar, honey, aspartame, saccharin or other artificial sweeteners, flavors, alcohol, local anesthetics, parabens.

#### INDICATIONS:

TEETHING GEL is indicated to treat the symptoms of teething in infants, especially to decrease the pain sensation and the reddening of the interested area.

#### COMPOSITION:

Xylitol, aqua, glycerin, Rosa damascena flower extract, xanthan gum, hyaluronic acid sodium salt (0,25%), potassium sorbate (0,1%), pectin, sodium benzoate (0,1%), citric acid, malva sylvestris leaf extract (0,05%), chamomile recutita flower extract (0,05%), aloe barbadensis leaf extract (0,05%).


#### USE AND DOSAGE:

Apply enough product to cover the interested area and gently massage the gums. Use preferably after meals and before sleeping in order to help the formation of the film and prolong the duration of the relief. Use 3-5 times per day, as needed. Recap after each application.

Is not recommended the use of the product for children under 6 months.






#### STORAGE AND CONSERVATION:


Store below 25 °C. The expiry date refers to the product intact and properly stored. Do not use beyond the expiration date on the package. Use within 30 days after the first opening. The residue or expired product can be disposed as normal household waste.






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LEAFLET  
Dimension: 120X150 mm

BACK SIDE

<b>WARNINGS:</b> <ul style="list-style-type: none"> <li>• The product must be used in the oral cavity.</li> <li>• Do not use in case of individual hypersensitivity to one or more of the components.</li> <li>• It is recommended to inform your doctor or pharmacist if you are using, have recently used or might use any other medication.</li> <li>• If symptoms do not improve, seek medical advice.</li> <li>• Recap after each application.</li> <li>• Expiry date is for intact product, correctly stored.</li> <li>• Do not exceed the recommended daily dose.</li> <li>• Do not use the product if the container is damaged or not intact.</li> <li>• Do not use beyond the expiry date printed on the package.</li> <li>• Use the product according to instructions.</li> <li>• Dispose of properly.</li> <li>• Keep the product out of reach of children.</li> <li>• Any serious incidents should be reported to the manufacturer and the relevant local authority, which will provide further advice.</li> </ul>	
<b>SIDE EFFECTS:</b> Based on scientific literature, there are no known or predictable adverse effects related to use of the product. In case of undesired effects during use, seek medical advice	
Tube of 15 ml	
Distributors	 Farmaceutici Procemsa S.p.A. SB Via Mentana 10 – 10042 Nichelino (TO)
<div style="text-align: right;">  0476   1130862 </div>	
Symbols description	
	Batch code
	Expiry date/ Use-by date

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	Manufacturer
	Consult the instructions for use for important cautionary information such as warnings and precautions.
	Consult instructions for use
	Do not disperse after use
	Store below 25°C
<b>REF</b>	Catalogue number
<b>MD</b>	Medical Device
<b>UDI</b>	UDI Symbol
<div> <div>Last version: October 2022</div> <div>1435219</div> </div>	