

Cacicol[®]

Poly (carboxymethylglucose sulfate) | RGTA[®]

Medical device

The Matrix Therapy



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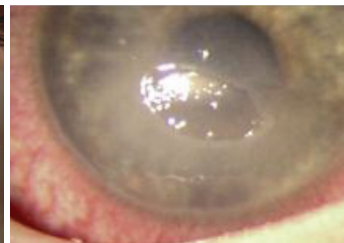
Medical device

- C Belongs to the family of the so-called “ReGeneraTing Agents” (RGTA®)⁽¹⁻³⁾
- C An analogue of Heparan Sulfate Glycosaminoglycans (HS GAGs) = Corneal ExtraCellular Matrix (ECM) components
- C The first therapeutic Matrix agent in ophthalmology intended for the management of chronic corneal wound healing such as :
 - > Persistent epithelial defects (PED)
 - > Neurotrophic keratitis/ulcers (NK)
 - > And persistent anterior corneal dystrophies with ulceration and associated pain



Persistent epithelial defects with erosions

Photo copyright M. UDZIELA



Neurotrophic ulcer (trigeminal nerve anesthesia)

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PILOT STUDY

Patients and methods⁽⁴⁾: n=10 patients (11 eyes)

A pilot, prospective, non-controlled study and compassion use

EYES	PATHOLOGIES	ETIOLOGIES / CAUSES	CONVENTIONAL TREATMENTS USED
6 eyes	Severe dystrophic cornea with chronic superficial punctuate keratitis	4 Limbic deficiency 3 Endothelial decompensation 1 Ichthyosis	Healing eye drops Lachrymal substitutes Anti-inflammatory
5 eyes	Painful corneal ulcers	1 Graft rejection 1 Immunological keratitis secondary 1 Chronic post trauma ulcer	

Clinical criteria:

- Tolerance and efficacy judged during a complete ophthalmic examination at D3, D7, D14, D21, D28, after 2 and 3 months
- Tolerance and safety judged on pain evaluation and functional inconvenience

Cacicol dosing regimen:

1 drop per week during 1 month and administered by the investigator

C Healing for patients with corneal ulcers⁽⁴⁾

- > **80% healed during the protocol (4 cases)**
 - 2 reversed when treatment stopped
 - 2 healed without reversion at the last visit
- > 1 case was characterized by stem cell deficiency and no improvement was noted but a decrease of pain clearly observed

Cacicol favored healing in almost corneal ulcers

C Efficacy on pain⁽⁴⁾

- > **D1 (inclusion visit):** score was 72.73 ± 7.86
- > **D7:** score decreased significantly with the first drops of treatment, 49.09 ± 14.46 ($p < 0.05$)
- > **D28 (M1):** score was 32 ± 15.49

Cacicol decreased significantly the score on VAS of pain between inclusion visit and month 3 (score: 55.71 ± 22.28 ($p=0.02$))

C Good tolerance⁽⁴⁾

- > No uneasiness during instillation
- > No worsening of the initial pathology
- > No occurrence of ocular inflammation or increase in ocular pressure
- > No general side effects

CLINICAL STUDY

Patients and methods¹⁾: n=11 patients

An uncontrolled, prospective, single-center clinical study

PATIENTS	PATHOLOGIES	ETIOLOGIES / CAUSES	TREATMENT AT THE TIME OF INCLUSION
11 patients	Corneal neurotrophic ulcer associated with complete corneal anesthesia	5 Post infectious keratitis 3 Limbal allografts due to chemical or thermal burn 1 Emergency penetrating keratoplasty 1 Neovascular glaucoma 1 Complication of toxic epidermal necrolysis	Preservative-free artificial tears (all patients during 15 days) 2% cyclosporine eye drops if appropriate

Criteria: efficacy and tolerance

Main outcome measures: healing of the corneal surface and best corrected visual acuity before and after RGTA therapy

Cacicol dosing regimen:

1 drop in the morning, on alternate days.

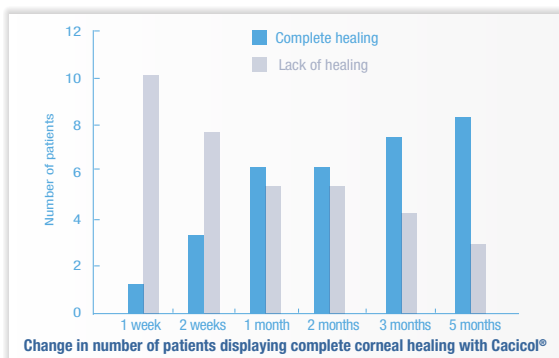
The treatment was stopped as soon as complete healing.

Decrease of mean area of ulcers⁽¹⁾

TIME	MEAN AREA OF NEUROTROPHIC ULCERS	p
Week 1	from 11.12% to 6.37%	p=0.0479
Week 2	to 4.24%	p=0.0142
Week 3	to 2.35%	p=0.0102
Week 4	to 1.56%	p=0.0054
After 2 months	1.41%	p=0.0051
After 3 months	0.33%	p=0.0065

Cacicol significantly decreased the mean area of ulcers during follow-up

Complete corneal healing⁽¹⁾

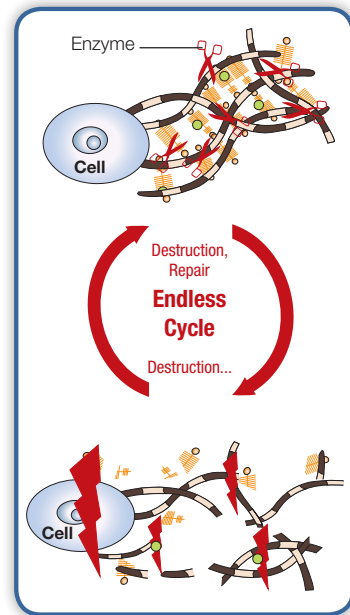
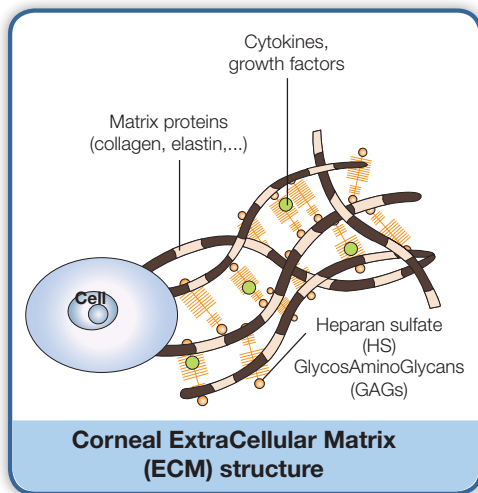


Cacicol favored corneal healing in 72.7% (8 out of 11 patients) patients after 8.7 weeks

- > Treatment failure observed in 3 cases (strong severity cases in regards to etiology), requiring amniotic membrane transplantation in 2 patients and penetrating keratoplasty in one
- > Mean corrected visual acuity did not differ significantly before and after treatment

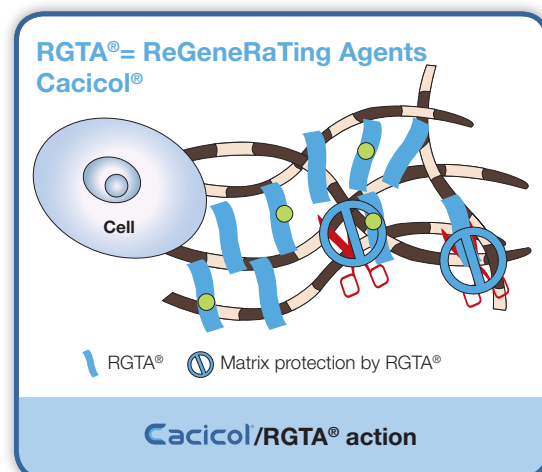
A UNIQUE MODE OF ACTION⁽¹⁻³⁾

When applied topically to a wound, **Cacicol**[®] penetrates into the damaged ExtraCellular Matrix (ECM)



Cacicol[®]

- Mimics the HS structure
- Replaces degraded HS to interact with structural proteins and growth factors
- Protects matrix proteins from degradation



Cacicol restructures and protects the corneal tissue

1 Aifa A. and al. Topical Treatment with a New Matrix Therapy Agent (RGTA) for the Treatment of Corneal Neurotrophic Ulcers. IOVS, 53(13),2012.8181-8185.

2 Baritault D., Caruelle J.-P. Les agents de régénération (ou RGTA) : une nouvelle approche thérapeutique. Ann Pharm Fr. 64.2006.135-144.

3 Baritault D. and al. CACICOL20[®], a New Matrix Therapy Device Improves Resistant Corneal Ulcers and Keratitis. 8th International Symposium on Ocular Pharmacology and Therapeutics (ISOPT). December 3-6,2009.109-113.

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Medical device

A simple dosage

1 to 2  in the affected eye(s) once a week until complete re-epithelialization

Ready and easy to use

agm Communication Getty image © Colorofline



Box of 5 sterile preservative-free unit doses Ophthalmic solution

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