

# "Formulación magistral en oftalmología"

Santiago de Compostela, octubre 2011

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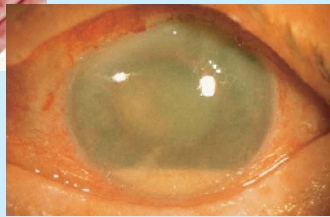
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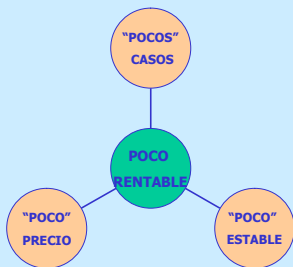
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POCA EVIDENCIA CLINICA  
POCAS INDICACIONES LEGALMENTE RECONOCIDAS  
MUCHA VARIABILIDAD CLINICA Y GALENICA

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# VARIABILIDAD GALENICA.

**Francoeur et al**  
**(J Glaucoma 1999 Aug; 8 (4): 242-6).**  
Variabilidad en la preparación de mitomicina C intraoperatoria en hospitales de Norteamérica.

33 variaciones en 21 hospitales  
(11 canadienses y 10 estadounidenses)

6 de los cuales (el 28% de los hospitales)  
potencialmente inestables.

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Results of the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1995; 113: 1479-96.

A New Topical Formulation for Preventing Venopuncture Induced Pain in Children. Reg Anesth Pain Med 2002; 27: 289-95

ESCRS study of prophylaxis of postoperative endophthalmitis after cataract surgery: Case for a European multicenter study. J Cataract Refract Surg 2006; 32:396-406

## North of England Evidence Based Guideline Development Project, 1996

### Categorización de la Evidencia

- I:** Ensayos clínicos controlados, metaanálisis o revisiones sistematicas bien diseñados.
- II:** Estudios controlados no aleatorizados bien diseñados (cohortes, casos y controles).
- III:** Estudios no controlados o consenso.

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## Topical Bevacizumab and Ocular Surface Neovascularization in Patients With Stevens-Johnson Syndrome

Harvey S. Uy, MD, PhD, Sha Chen, MD, and Robert Edward Ang, MD

**Purpose:** To evaluate the effect of topical bevacizumab on ocular surface neovascularization among patients with Stevens-Johnson syndrome.

**Methods:** This was a retrospective, interventional case report. Three eyes of 2 patients with Stevens-Johnson syndrome were treated 4 times daily for 2 weeks with topical bevacizumab. The primary end point was the degree of ocular surface neovascularization, defined as the presence of conjunctival injection and accumulation of subconjunctival vessels.

**Results:** Both patients completed the 2-week observation period and reported that it significantly improved ocular comfort. At the end of the study period, ocular surface neovascularization was absent in 1 eye. Because ocular surface neovascularization, conjunctival injection, and subconjunctival injection are clinical signs of Stevens-Johnson syndrome, the absence of these signs was noted.

**Conclusions:** Topical bevacizumab is well tolerated and may be effective in improving ocular comfort and reducing symptoms of ocular surface neovascularization, conjunctival injection, and conjunctival injection in patients with ocular surface disease caused by Stevens-Johnson syndrome. Further randomized, controlled studies are needed to fully evaluate the long-term effects of this novel treatment.

**Key Words:** bevacizumab, ocular surface disease, neovascularization, Stevens-Johnson syndrome  
(Cataract 2008;27:76-77)

neovascularization for these patients has led to the development of extremely complex surgical procedures, such as the resection of conjunctival fibrotic tissue, scleral resections, and enucleation and resection of the globe. The use of topical bevacizumab (PULIS, and Key Pharmaceuticals, Inc., Fremont, CA) has been reported to be effective in the treatment of ocular surface neovascularization in patients with Stevens-Johnson syndrome.<sup>1-3</sup> These methods have not been widely used because of their high associated costs, need for specialized skills and equipment, and risk of poor long-term success rates.<sup>4,5</sup>

OSN is a prominent feature of SJS that results in visual loss because of accompanying scarring and lipid deposition.<sup>6</sup> There is extensive evidence supporting a causal role for vascular endothelial growth factor (VEGF) in maintaining OSN.<sup>7-12</sup> Large clinical trials have shown that anti-VEGF antibodies can normalize VEGF and reduce regression of choroidal neovascularization in RVO.<sup>13-15</sup> A recent animal study showed regression of choroidal neovascularization after topical administration of bevacizumab (Genentech, South San Francisco, CA).<sup>16</sup> We report here a specific, clinically controlled regression of OSN, sclerotic epithelium, and conjunctival injection, with resulting visual improvement after application of topical bevacizumab.

### CASE REPORTS

The case reports detailed an 80-year-old female patient who was hospitalized for the treatment of SJS. She had been treated for the 10th day with intravenous methylprednisolone in accordance with the principles of the Guidelines for the treatment of SJS. She had been hospitalized for 10 days and had been treated with intravenous methylprednisolone for 10 days.

Published 10 June 2010, doi:10.1136/bmj.m2469  
Cite this as: BMJ. 2010;340:m2469

## Research

### Bevacizumab for neovascular age related macular degeneration (ABC Trial): multicentre randomised double masked study

Setting Three ophthalmology centres in the United Kingdom

Participants 131 patients (mean age 61) with wet age related macular degeneration randomised 1:1 to intervention or control

Conclusions Bevacizumab 1.25 mg intravitreal injections given on part of a bi-weekly variable regimen regimen is superior to standard care (bevacizumab sodium vertecicin, sham), with low rates of serious ocular adverse events. Treatment improved visual acuity on average at 54 weeks

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*Farm Hosp 1990; 20 (1) - 67*  
per elaboresse que, havent investigat el cas, no es un producte no autoritzat que, quan s'utilitza, no ha de procurar-se la cobertura legal. Si no existe el cas d'un determinat antibiòtic **no puede elaborarlo** si no cuenta con una autorización concreta, por ejemplo, como uso compasivo para determinado enfermo, puesto que utiliza una forma farmacéutica y una indicación no aprobadas en España. Y ello por duro que parezca. Su responsabilidad ya no es sólo si algo malo le ocurre al paciente, sino por el sólo hecho de elaborarlo y dispensarlo. Si

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## Estudio jurisprudencial de la responsabilidad legal del personal sanitario en la reformulación de medicamentos

I. J. Reche-Castex, J. M. Alonso-Herreros<sup>1</sup>

Vol. 29, No. 3, pp. 369-392, 2023

### Resumen

**Objetivo:** Analizar la responsabilidad del personal sanitario al elaborar medicamentos formulados en la vida diaria, tanto dentro como fuera de un laboratorio de especialidades farmacéuticas, desde la jurisprudencia del Tribunal Supremo y de Audiencia Nacional.

**Método:** Búsqueda y análisis de jurisprudencia y estudios jurídicos en los temas de casos "El Doctor", "Omnium sanctorum" e "Elyx".

**Resultados:** El personal sanitario tiene una obligación de medios, no de resultado. El farmacéutico, dentro de los límites que constituye la "Lex Artis", y sus preparadores, al elaborar los medicamentos hospitalarios, tanto a esas normas de calidad, la investigación es acuciosa en la vida de la empresa o la industria del paciente pueden ser componentes negligentes. Se mencionan algunos casos en la jurisprudencia. En los casos en que se cumplen las normas de calidad, incluyendo la evidencia con las excepciones factuales, existen algunas situaciones que no son negligentes, como en el caso de "Lex Artis" de la industria, los profesionales tienen una obligación de medios.

**Conclusiones:** La reformulación de especialidades farmacéuticas, regulada en la Ley Art. 6, es una práctica aceptada por el Tribunal Supremo y la Audiencia Nacional, siendo causa de responsabilidad si se incurre en los errores o cambios no autorizados o no autorizados.

**Palabras clave:** Responsabilidad, Negligencia, Elyx, Puntos de venta, Industria.

EDITORIAL (Revista) 2023, 34(3): 369-392

## El real decreto de medicamentos en situaciones especiales y la farmacotecnia hospitalaria

The Spanish royal decree for medicines under special circumstances and hospital pharmacotechnology

R. García Salom<sup>1</sup> y J.M. Alonso Herreros<sup>1,2</sup>

1. Fórmulas magistrales CON evidencia científica, (sunque baja) y estudios de estabilidad y caracterización química.

RECOMENDACIÓN:  
● Proponer su inclusión en la Guía Farmacoterapéutica del hospital, en las condiciones que la Comisión de Farmacoterapia estime oportuna.

2. Fórmulas magistrales de elaboración tradicional (habitual SIN evidencia científica, (= sin ensayos clínicos)).

a. Con un medicamento líquido sólido, (ej. antibióticos en inyectables).

RECOMENDACIÓN:  
● SEGUIR PREPARANDOS (ya que forma parte de la LEX ARTIS de algunas especialidades médicas.)

b. Con un medicamento tópico débil.

RECOMENDACIÓN:  
● Realizar los procedimientos caracterizadores para su aprobación por las comisiones de farmacia, incluyendo el consentimiento informado de paciente o representante legal, y los aspectos galénicos.

3. Fórmulas magistrales INFRECUENTES, ya preparadas con anterioridad, SIN evidencia científica.

a. Con un medicamento tópico sólido, (ej. antibióticos en infecciones).

RECOMENDACIÓN:  
● Elaborar protocolo y pasar por comisión farmacia.  
● Exigir consentimiento informado.

● Seguir preparándolas, pero con recogida de datos obligatoria para su control y el farmacéutico responsable del centro o grupo de trabajo.

b. Con un medicamento tópico débil.

RECOMENDACIÓN:  
● Preparar la FM.  
● Exigir consentimiento informado.  
● Exigir recogida de datos obligatoria para su control y difusión por los responsables del centro o grupo de trabajo.

4. Fórmulas magistrales de nueva solicitud SIN evidencia científica y SIN alternativa terapéutica.

a. Con un medicamento tópico sólido, (ej. antibióticos en infecciones con microorganismos multiresistentes a otros fármacos, etc.).

RECOMENDACIÓN:  
● PREPARAR.  
● Exigir el consentimiento informado.  
● Establecer con apoyo de la dirección y comisión de farmacia, medida no para exigir recogida de datos obligatoria para su análisis y difusión.

b. Con un medicamento tópico débil.

RECOMENDACIÓN:  
● NO PREPARAR.  
● Si se desea utilizar, exigir paso por comisión de ensayos clínicos para que se realice en el seno de un

ARCHIVE OF Ophthalmology 2009; 52: 257-260 EDITORIAL

## LA RESPONSABILIDAD DEL OFTALMÓLOGO AL EMPLEAR MEDICAMENTOS NO RENTABLES A LOS LABORATORIOS

Los que les resultan más rentables. Las consecuencias de esta práctica, e injusta situación las están sufriendo tanto los pacientes que tienen limitado su acceso a un recurso terapéutico eficaz y barato para su enfermedad, como los oftalmólogos que se ven obligados a realizar una serie de gestiones administrativas costosas de autorización por vía compartiva. Ante los documentos, los cuestionarios autorizados adicionales, informe oftalmológico de cada paciente, etc.) e incluso en ocasiones manipulaciones de los fármacos con el consiguiente riesgo de toxicidad que conlleva la farmacia casera o «kit-clinic pharmacy» de la Hermita anglosajona (1), que pueden evitarse si existieran alternativas presentaciones comercializadas para uso oftalmológico.

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ASHP Report: Pharmacy-prepared ophthalmic products

### ASHP technical assistance bulletin on pharmacy-prepared ophthalmic products

ASHP Report: 2003-08-19/23

**• Estéril.**

Key words	Brand	Form	Concentration	Pk	St. 333 mg/mL	Insertion
LL-Medication	Albion	Injection	Solution	1%	200 (Albion) 200 (Albion) 200 (Albion)	Insertion, dose = 2.4500 mg/mL in 10 (Albion) 1 (Albion)

Chemistry of Albion 200 (Albion) 200 (Albion) 200 (Albion)

Terminology: **Insertion-Ophthalmology, 2003, 52: 257-260**

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Microsoft Word - Ketovonazol

**KETONAZOLE**

**CLINICAL ALLEGATIONS**

**1. THERAPEUTIC USES**

**1.1. KERATOMYCOSIS**

**1.1.1. ADULTS**

100% success rate in the treatment of keratitis (see also clinical data in the package insert for KETONAZOLE). Results are also effective in the treatment of keratitis (see also clinical data in the package insert for KETONAZOLE).

**2. SURTACRYL: This contact lens is effective for the treatment of keratitis (see also clinical data in the package insert for SURTACRYL).**

**3. ADULTS**

In a study comparing ketonazole 1% eye drops with 0.1% ketonazole (200 mg/100 mL) eye drops, the 1% eye drops were found to be more effective (90% success rate) than the 0.1% eye drops (70% success rate) in the treatment of keratitis. These results are based on the number of cases treated. The number of cases treated with ketonazole 1% eye drops was significantly higher than the number of cases treated with ketonazole 0.1% eye drops. In a study comparing ketonazole 1% eye drops with ketonazole 0.1% eye drops, the 1% eye drops were found to be more effective (90% success rate) than the 0.1% eye drops (70% success rate) in the treatment of keratitis. These results are based on the number of cases treated. The number of cases treated with ketonazole 1% eye drops was significantly higher than the number of cases treated with ketonazole 0.1% eye drops.

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- pH, osmolaridad y lágrimas artificiales.

Lágrimas artificiales propiedades fisicoquímicas similares a las lágrimas naturales.

*¿Podría ser un excipiente universal para colirios?*

Numerosa marcas comerciales, con varios componentes, y por tanto, numerosas interacciones potenciales.

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**Osborn E, et al.** The stability of ten antibiotics in artificial tear solutions. *Am J Ophthalmol* 1976; 82:775-80

Incompatibilidades entre lágrimas artificiales y *vancomicina*, *neomicina*, y *cefazolidina*

**Moreno S, y col.** Estabilidad de colirios de vancomicina mediante cromatografía líquida de alta resolución. *Cienc Pharm* 1996; 6(2): 77-81

**Monserrat V, y col.** Influencia de la concentración, temperatura, y vehículo sobre la estabilidad de un colirio de amikacina. XLI Congreso de la SEFH. Sevilla 1996.

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**Box 81.1**

Preparation of Sterile Topical Antibiotics  
Adapted from Basic Clinical and Science Course 2000-2001,  
Division of Ophthalmology and Eye Care, Johns Hopkins University,  
Baltimore, MD.

**Ingredients:**  
 1.0 g (10 mg/ml) of ciprofloxacin hydrochloride  
 0.25 g (2.5 mg/ml) of tobramycin sulfate  
 1.0 g (10 mg/ml) of vancomycin hydrochloride  
 1.0 g (10 mg/ml) of gentamicin sulfate  
 1.0 g (10 mg/ml) of amikacin sulfate  
 1.0 g (10 mg/ml) of rifampin

**Procedure:**  
 1. Weigh 10.0 g of sterile distilled water into a 100 mL beaker.  
 2. Add 1.0 g of ciprofloxacin hydrochloride to the solution.  
 3. Add 0.25 g of tobramycin sulfate to the solution.  
 4. Add 1.0 g of vancomycin hydrochloride to the solution.  
 5. Add 1.0 g of gentamicin sulfate to the solution.  
 6. Add 1.0 g of amikacin sulfate to the solution.  
 7. Add 1.0 g of rifampin to the solution.  
 8. Mix thoroughly.  
 9. Filter through a 0.45 µm filter into a sterile container.  
 10. Sterilize the solution by autoclaving at 121°C for 15 minutes.  
 11. Dispense into sterile containers.  
 12. Label and store at room temperature.

**Notes:**  
 - This solution is for use as a vehicle for injection.  
 - It is not intended for use as a vehicle for injection.  
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 - It is not intended for use as a vehicle for injection.

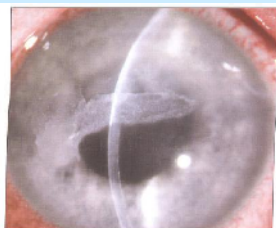


Fig. 81.81 Crystalline deposits of proflonate in a contact lens on the cornea.

**Krachmer et al. CORNEA (2ª Ed). Elsevier-Mosby 2005**  
 Capítulo 81 - pg 1023

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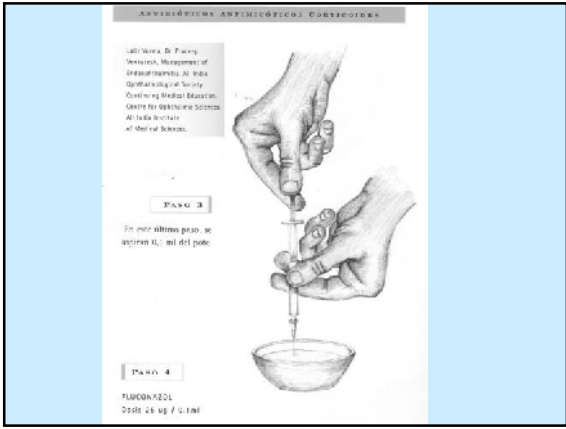
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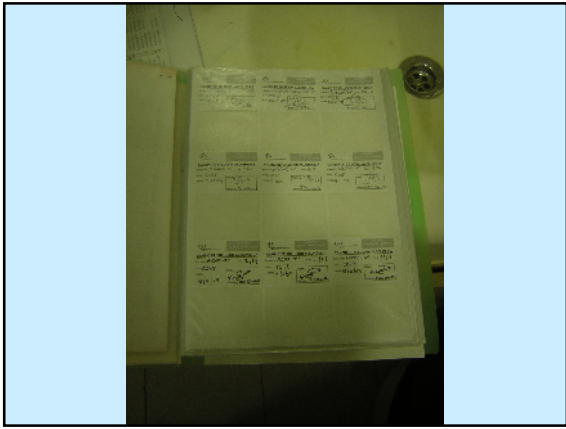
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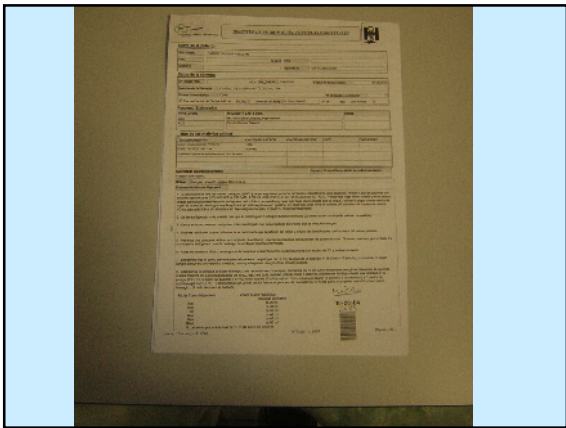
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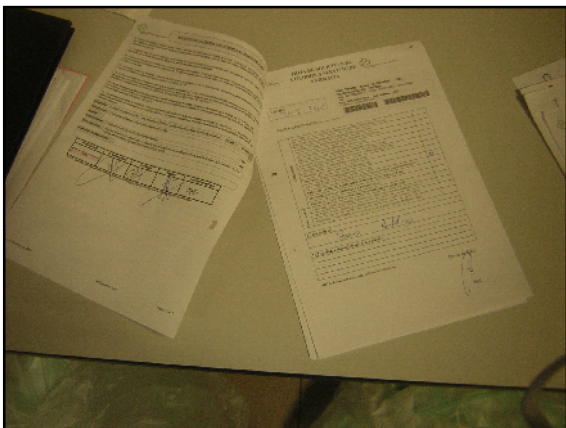
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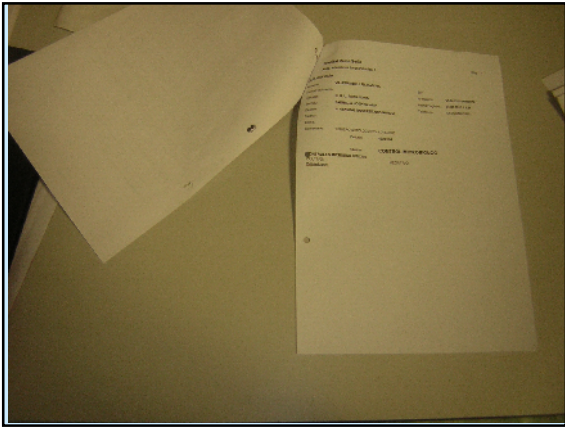
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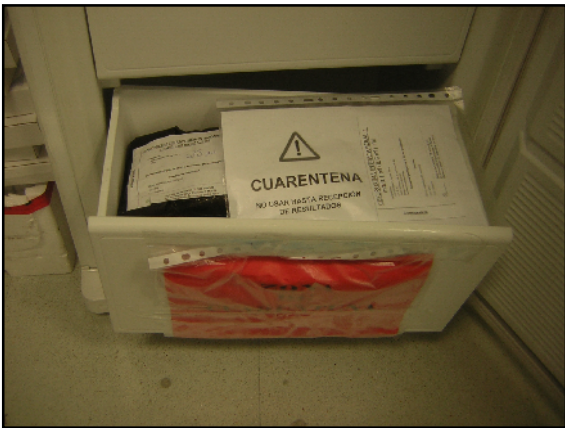
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**Seguimiento adherencia pacientes externos**

Diagnóstico:

Edad:  Sexo:

Nombre y apellidos	Fecha consulta	Valor de la consulta

Fecha	Nº de medicación	Nº de dosis	Nº de dosis administradas	Nº de dosis dispensadas	Nº de dosis recibidas
10/01/2018	1	0	0	0	0
14/01/2018	2	0	0	0	0

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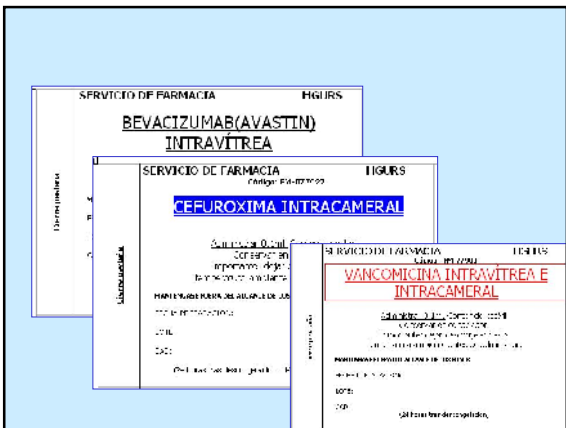
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**MEJORAS PENDIENTES:**

- Cabina clase A en entorno clase A

- Trazabilidad en la elaboración con código de barras

- Control analítico cuali y cuanti previo a la liberación de lotes.

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