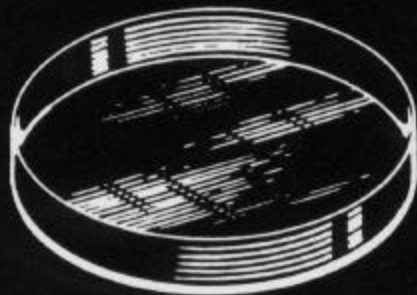


**Broad Spectrum
Antimicrobial**
for
Topical Application



CLORPACTIN[®] WCS-90
brand of
SODIUM OXYCHLOROSENE

FOR PHYSICIAN'S REFERENCE ONLY



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for
Topical Application



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Guardian Laboratories

a division of



UNITED-GUARDIAN, INC.

230 Marcus Blvd. • P.O. Box 18050 • Hauppauge, New York 11788

Tel: (631) 273-0900

800-645-5566

FAX: (631) 273-0858

www.u-g.com

INTRODUCTION and GENERAL INFORMATION

With the increasing incidence of bacterial resistance and chemotherapeutic intolerance, the existence of an agent which combines a high degree of activity against even the most resistant micro-organisms together with a very great safety factor can contribute much to the armamentarium of the physician and the surgeon.

Although, in the strict sense a topical agent, Clorpactin WCS-90 (sodium oxychlorosene), because of the non-toxic nature of its recommended concentrations, can be tolerated safely wherever irrigation can be practically carried out. Its freedom from allergenicity makes it extremely useful where repeated or constant applications are necessary. It has been in use since 1955 in a quantity equivalent to many millions of liters of solution, yet no indications of a toxic nature have appeared in the medical literature, despite the varied nature of the conditions treated and the variations in the methods of application.

Historically, this chemotherapeutic agent can be regarded as a development from modified Dakin's solution to which it is chemically related. Thus, Clorpactin WCS-90 can be considered a form of Dakin's solution developed to the ultimate extent as to effectiveness and safety. Therefore, the term "Modern Dakinization" which has been given to sodium oxychlorosene is an apt phrase, even though the latter does differ from Dakin's solution perhaps in as many ways as it is similar.

Clorpactin WCS-90 (sodium oxychlorosene) is a stabilized organic derivative whose generic name has been designated as sodium oxychlorosene.⁽³⁰⁾ It is the complex formed from the combination of the sodium salt of dodecylbenzenesulfonic acid and hypochlorous acid. Dakin's solution, on the other hand, is an inorganic solution of buffered sodium hypochlorite. Thus the latter has a pH of 9.3 to 10.2 and is irritating at a pH of less than 9.3 since it has a tendency to split out chlorine. Thus it is highly toxic at any pH considerably lower than its established one. On the other hand, sodium oxychlorosene has a normal pH of 6.5 to 6.9 and in this pH range is not irritating to open wounds.

In this connection, it is of further interest to note the tremendous difference in activity between hypochlorous acid derivatives at various pH levels when measured in activity against resistant spores. This is borne out by Tilley and Chapin in 1930,⁽¹⁾ and Charlton and Levine in 1935.⁽²⁾

TABLE I**BACTERICIDAL EFFICIENCY OF HYPOCHLOROUS ACID BUFFERED TO VARIOUS pH LEVELS (+ = growth; - = no growth)**

pH	AVAILABLE CHLORINE P.P.M.	CONTACT TIME			
		15 MIN	30 MIN	45 MIN	1 HOUR
10	100	+	+	+	+
9	40	+	+	+	-
9	50	+	+	-	-
8	10	+	-	-	-
6	4	-	-	-	-

The importance of the pH as it affects the germicidal properties of such solutions is even more dramatically demonstrated by Rudolph and Levine in 1941,⁽³⁾ as shown in Table II.

TABLE II**TIME REQUIRED FOR 25 P.P.M. AVAILABLE CHLORINE TO KILL '99% OF VERY RESISTANT SPORES AT VARIOUS pH LEVELS**

pH	Time (minutes)
6	2 ½
7	3 ⅓
8	5
9	19 ½
9.35	35 ½
10	no effect

Potentiometric studies have shown that the oxidizing power of hypochlorite solutions are greater than that of chlorites* and greater still as compared with that of peroxide. Figure 1 shows that the oxidation potential of hypochlorite solutions increases rapidly as the pH is decreased.

*It should be noted that very few metals are completely resistant to chlorine dioxide, as compared to hypochlorous acid, which is the basis of Clorpactin WCS-90.

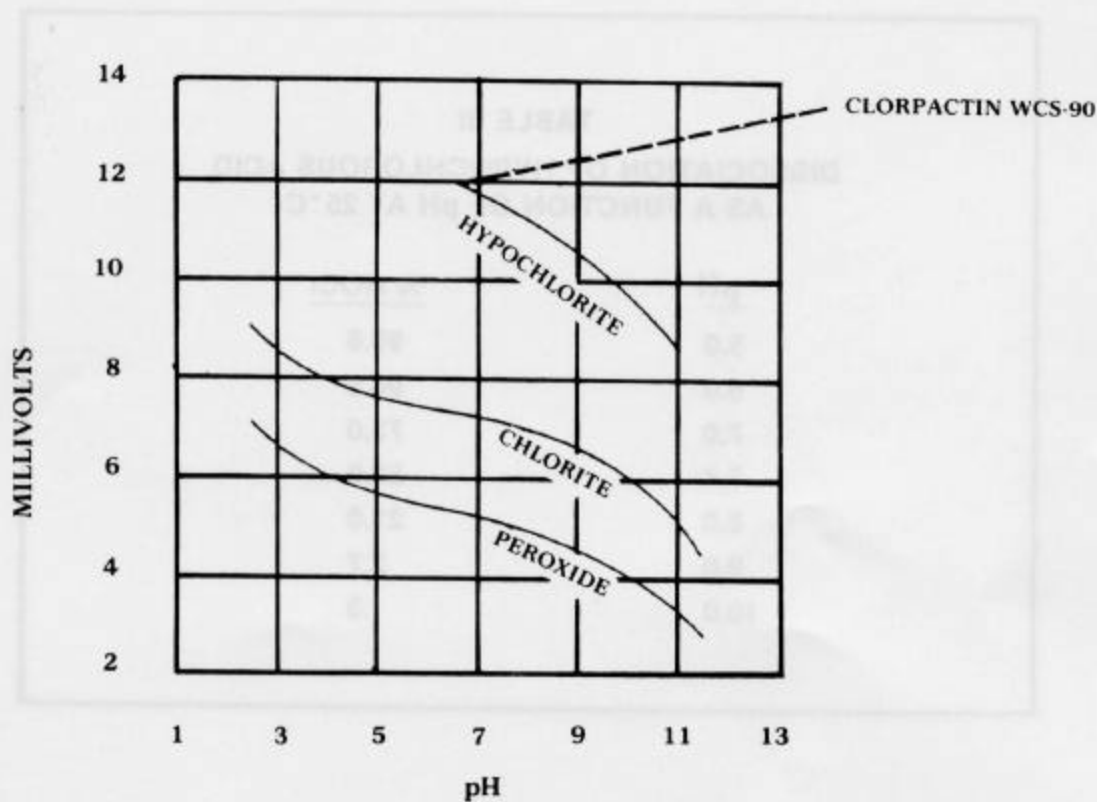


Figure 1. Oxidation potentials referred to the normal hydrogen electrode. [32]

Hypochlorous acid has outstanding microbicidal power. This is generally attributed to its ability to diffuse through cell walls and thereby reach the vital parts of the microbial cell; therefore, the hypochlorite ion has little bactericidal effect since its negative charge impedes penetration of the cell wall. Thus the microbicidal power of a solution of hypochlorite is directly proportional to the hypochlorous acid concentration. That part of the measurable available chlorine which is present as hypochlorous acid is responsible for its microbicidal effectiveness.

The effect of pH on the degree of dissociation of hypochlorous acid is shown in Table III. While a pH of above 9 is necessary for stability, the release of HOCl becomes more complete as the pH decreases. Thus, in standard hypochlorites, there is from 0.1 - 0.3% free HOCl; in Dakin's Solution, this increases to about 2%; in Clorpactin WCS-90, this becomes 75%. This is responsible for the enormous microbicidal activity of the latter, while the neutrality of the Clorpactin solutions account for its physiological tolerance.

TABLE III
DISSOCIATION OF HYPOCHLOROUS ACID
AS A FUNCTION OF pH AT 25°C

<u>pH</u>	<u>% HOCl</u>
5.0	99.6
6.0	96.5
7.0	73.0
7.4	50.0
8.0	21.0
9.0	2.7
10.0	.3

GENERAL

Because of its high anti-microbial activity Clorpactin WCS-90 (sodium oxychlorosene) for the sake of designation, is considered to be a **biocide**, for its action is markedly cidal rather than inhibitory. In concentrations ranging from 0.2-0.5% depending upon conditions, its solutions are destructive to all micro-organisms, regardless of their type or normal resistance to other agents. By a combined process of simple oxidation and hypochlorination through ionized and un-ionized hypochlorous acid ($\text{OCl}^- + \text{HOCl}$) a rapid loss of viability appears to take place in the micro-organism followed by its death and, subsequently, by complete solubilization due to the destruction of the protoplasmic contents of the microbial cell. Thus, exposure of the

organism in a microscopic field to the action of the solution results in a clearing of the field as the organisms dissolve in the surrounding aqueous medium.

Despite this enormous activity, this solution has no effect upon solid tissue (although it naturally will destroy a detached squamous cell with the same avidity with which it attacked a bacterium). Its advantages as a topical chemotherapeutic agent can therefore be summed up as follows:

(1) Complete antimicrobial spectrum when employed topically in the recommended concentrations upon infections which can be reached adequately by copious irrigation. Its action is rapid and complete, according to laboratory reports, upon both Gram-negative and Gram-positive bacteria, fungi, yeast, mold, viruses and spores.

(2) No adverse effect on normal tissue or epithelial growth in these same concentrations.

(3) No development of resistant organisms.

(4) No systemic toxicity no matter how long the solution is used nor in what quantity, as long as the maximum recommended concentrations are not exceeded.

(5) No development of intolerance or allergenicity by reason of prolonged use as in (4) above.

Because of this unusual combination of properties, it is only natural that the medical literature on its use, particularly on refractory infections which are resistant to most or all other forms of topical chemotherapeutic agents should be quite extensive, covering a period from 1954 to the present.

It is the purpose of the following, therefore, to set forth some of the procedures described in this literature and some of the specific recommendations abstracted from some of these studies and reports.

ACTION AND USES: Clorpactin WCS-90 (sodium oxychlorosene) solutions are used for treating localized infections, particularly when resistant organisms are present; to remove necrotic debris in massive infections or from radiation necrosis; to counteract odorous discharges; as a pre- and post-operative irrigant and for the cleansing and disinfection of fistulae, sinus tracts, empyemas and wounds.

ADMINISTRATION AND DOSAGE: As a topical agent, it is applied by irrigation, instillation, spray, soaks or wet compresses, preferably

thoroughly cleansing and disinfecting all exposed affected areas by means of copious flow through intermittent or continuous gravity flow or by means of a syringe, in order to provide quantities of fresh solution to replace the volatilized active ingredient (hypochlorous acid) and to remove the organic waste and debris from the site of the involvement. Instillations should be repeated at frequent intervals; compresses should be renewed often, or maintained in conjunction with a gravity flow system. Generally applied as the 0.1-0.5% solution in water or isotonic saline.

It is interesting to note that Clorpactin solutions have been reported in one or more of the studies listed in the reference as being bactericidal, fungicidal and/or virucidal against each of the following organisms:

TABLE IV

ORGANISM

<i>Aerobacter aerogenes</i>	<i>Mycobacterium tuberculosis</i>
<i>Bacillus anthracis</i>	<i>Mycobacterium tuberculosis</i> var. <i>hominis</i>
<i>Bacillus stearothermophilus</i>	<i>Mycobacterium tuberculosis</i> (H 37 Rv)
<i>Bacillus subtilis</i>	<i>Pasteurella intermedium</i>
<i>Brucella</i>	<i>Pasteurella pestis</i>
<i>Candida albicans</i>	<i>Proteus</i>
<i>Clostridium perfringens</i>	<i>Pseudomonas aeruginosa</i>
<i>Clostridium sporogenes</i>	Rabies virus
<i>Clostridium tetani</i>	<i>Salmonella saccharomyces</i>
<i>Corynebacterium diphtheriae</i>	<i>Serratia marsescens</i>
<i>Cryptococcus</i>	<i>Shigella dysenteriae</i>
<i>Entamoeba coli</i>	<i>Staphylococcus pyogenes</i> var. <i>aureus</i>
<i>Entamoeba histolytica</i>	<i>Streptococcus faecalis</i>
<i>Hemophilus pertussis</i>	<i>Streptococcus pyogenes</i>
<i>Klebsiella pneumoniae</i>	<i>Vibrio comma</i>
Lansing poliomyelitis virus	Yeast, molds, bacteria
<i>Micrococcus pyogenes</i>	

I. SURGERY

A. GENERAL

For surgical irrigation, in the preparation of the skin prior to surgery or in the treatment and prevention of surgical infections, the concentration employed is 0.4 per cent. (To prepare a solution of such concentration, the contents of a freshly opened 2 gm. bottle is dissolved in 500 cc. of distilled water, preferably sterile, or sterile saline.) The solution can be prepared in a stainless steel basin, in glass or porcelain or even in plastic. (However, the use of metal containers should be limited to high quality stainless steel.) (Also, see "Preparation of Solution".)

For preparation of the skin, the solution should be in contact with the area to be incised for at least 3 minutes.

For irrigation, as in the peritoneal cavity during surgery, copious quantities of the solution are used and the irrigation repeated every 60 minutes if the operation takes longer than an hour. For shorter procedures, irrigation is done at the beginning of surgery and repeated immediately prior to closure. In the 0.4% concentration it is well tolerated within the peritoneal cavity, but to avoid any edematous reaction which may result from the hypotonic nature of the solution prepared with tap or distilled water, isotonic saline is employed advantageously. The excess solution is aspirated following the recommended contact time.

DuVal and Howard⁽¹⁵⁾ compared Clorpactin WCS-90 (sodium oxychlorosene) in a 0.4 per cent solution with a surgical soap containing hexachlorophene. Surgical patients were prepared for operation by scrubbing the operative site for 5 minutes either with 0.4 per cent Clorpactin or the hexachlorophene soap. As the operation proceeded, the wound was irrigated once every hour and again at the time of closure either with the 0.4 per cent solution or with sterile saline, respectively. Each irrigation was continued for one full minute. The study was conducted over a period of one year and terminated after 1,000 cases had been studied. Since random selection of cases was provided for by the flip of a coin, there were actually 511 cases in the hexachlorophene group and 489 in the Clorpactin series.

In clean cases, the incidence of wound infection was 12/262 (4.6 per cent) for hexachlorophene and 5/275 (1.8 per cent) in the Clorpactin group. In contaminated cases, the incidence of infection was 22/249 (9.2 per cent) for hexachlorophene and 15/214 (7.5 per cent) for Clorpactin.

B. ABDOMINAL SURGERY

Gliedman and his associates⁽¹⁴⁾ compared 1 per cent neomycin with the 0.4 per cent solution for impromptu bowel cleansing and sterilization in dogs. With both solutions the bacterial count was rapidly reduced. However, yeast and mold response to neomycin was erratic and unpredictable. Following 200 cc. of Clorpactin WCS-90 (sodium oxychlorosene), the wash fluid was routinely sterile for yeasts and molds as well as bacteria. In one instance, following the latter, even the mucosal biopsy was sterile.

C. PLASTIC SURGERY

Swanker⁽⁸⁾ reported the use of Clorpactin WCS-90 (sodium oxychlorosene) preoperatively and as a wet dressing postoperatively in a series of 164 cases involving plastic surgery. The concentration of the solution used was 0.25 per cent and no infections occurred. The operative areas were even free of the minute collections of purulent material frequently seen in this type of surgery. In addition to its antiseptic properties, the solution was also found to have a deodorant effect. Confirmatory information on the use of the product in abdominal surgery can be found in the work of Turell⁽¹⁶⁾ and in a condensation of the 1959 meeting of the American Chemical Society.⁽¹⁷⁾

II. UROLOGY

A. URINARY TRACT INFECTIONS

Clorpactin WCS-90 (sodium oxychlorosene) is highly effective in the treatment and prevention of urinary tract infections due to a wide variety of organisms. The following reports have appeared:

Baker and Callahan ⁽²²⁾	interstitial cystitis
Bunts (and, by invitation, Hoffman) ⁽²³⁾	bladder
Chenoweth and Clawater ⁽⁹⁾	interstitial cystitis in children
Flocks and Kadesky ⁽²⁴⁾	{ tuberculous cystitis; interstitial cystitis
Graham ⁽²⁵⁾	bladder
Lattimer and Spirito ⁽¹¹⁾	{ tuberculous cystitis; cystitis due to <i>Pseudomonas aeruginosa</i>
O'Connor ⁽²⁶⁾	interstitial cystitis
Warres ⁽²⁷⁾	interstitial cystitis
Wishard, Nourse and Mertz ⁽²⁸⁾	interstitial cystitis

B. INSTILLATION INTO THE BLADDER

For instillation into the bladder, the usual concentration is 0.2 per cent. Several instillations per treatment, with one treatment each five to seven days, are required for interstitial cystitis or tuberculous cystitis. In cases of infection due to a resistant organism which is capable of rapid multiplication, one treatment or even more per day are given. The initial instillation may cause discomfort in some patients, and, therefore, for the first treatment, the concentration is 0.1 per cent. For the prevention of infection in cases of cord bladder and indwelling catheter, a concentration as low as 0.02 per cent⁽²⁵⁾ appears adequate. Instillations are repeated at suitable intervals depending upon the symptomatic response of the patient.

It must be emphasized, since urine or organic debris is capable of neutralizing the hypochlorous acid, that giving a single instillation per treatment is not recommended. The initial instillation can be considered to be completely neutralized by the residual urine, and, therefore, hardly effective in attaining the desired results. The second and, if possible, a third instillation at intervals of several minutes into the bladder are needed in the cases of interstitial cystitis and for the contracted bladder. Also, retaining the solution for more than several minutes is without justification, and may involve unnecessary discomfort because all of the hypochlorous acid has become inactivated in contact with the bladder wall within 2-3 minutes. As an office procedure, this technique will involve filling the bladder to maximum tolerable capacity without overdistention as compared with the

original procedure recommended by O'Connor⁽²⁶⁾ in which the bladder is dilated moderately with the solution (0.2%) to attain the desired results.

Interstitial cystitis is a use of Clorpactin WCS-90 that has evolved from studies, articles, and other communications initiated by physicians over the many years the product has been available. To summarize this use, the following information is provided as guidance. Cystoscopy should be done before each treatment to determine bladder capacity and if the bladder is perforated or torn (in which case treatment should not be initiated). The patient's bladder should be emptied, and then filled to capacity but do not employ over distention. Use gravity feed and do not exceed 30 cm. of pressure. Each treatment should consist of two to three instillations with a dwell time of 2-3 minutes per instillation and several minutes between instillations. Do not use a concentration higher than 0.1% for the first treatment and then no higher than 0.2% for subsequent treatments. Repeat treatment every 4-5 days for at least 5 treatments. Improvement should be seen by the fifth treatment but seven or eight treatments may be necessary. If a period of 10 days or more elapses between treatments, the series of treatments should begin again. If the treatment is successful, the results may last from several months to as much as a year or more before treatment may have to be repeated. Mild to moderate pain is not unusual and can be treated with an OTC analgesic, but a stronger prescription analgesic may be required.

III. GYNECOLOGICAL

A. VAGINITIS AND CERVICITIS

Since this solution is rapidly effective against *Trichomonas vaginalis* as well as other organisms that cause vaginitis and cervicitis, it has been found helpful in the control of these conditions⁽¹³⁾

B. INTRAVAGINAL USE

For the treatment of vaginitis and cervicitis, it is prepared in a 0.4 per cent concentration. A moderate excess of solution is introduced intravaginally. After three minutes a tampon is inserted and left in place for a minimum of thirty minutes. Treatment is given every twelve hours until the infection has been eradicated.

IV. PROCTOLOGY

A. RECTAL USES

The powerful bactericidal, fungicidal, and virucidal properties combined with its nontoxicity in use concentrations^(8, 10, 19) make the solutions ideal for the chemotherapeutic treatment of various refractory infections of the lower intestinal tract. Proctitis, ulcerative colitis, fistulae and sinus tract infections; amebiasis, anusitis, and mold or yeast overgrowth, particularly in the rectum, resulting from the increased use of antibiotics—all can be treated advantageously, without danger of toxic absorption, allergenicity excessive irritation, or development of resistance on the part of the microorganisms.

Cleansing and sterilization of the bowel, prior to resection, in cases of surgery of unprepared bowel, can be accomplished by irrigating with a 0.4 per cent solution over a ten-minute period without danger of absorption and respiratory arrest reported to occur with some antibiotics.⁽¹¹⁾

Even organisms capable of developing resistance to most chemotherapeutic agents are rapidly destroyed by Clorpactin WCS-90 (sodium oxychlorosene) solutions.⁽¹²⁾

Furthermore, such solutions (a) exhibit pronounced wetting properties which assist in softening impacted stools; (b) are solvents for necrotic debris, particularly resulting from radiation necrosis; and (c) liberate hypochlorous acid in vapor form which is lethal to microorganisms even beyond the reach of the solution.

B. RECTAL AND COLONIC USE

The 0.4 per cent solution is prepared as described for surgical use.

1) As an enema in the treatment of colitis or proctitis as well as in routine proctologic examination:

Prepare a 0.4 per cent solution by stirring the powder slowly into 1 pint of warm water. After several minutes the enema bag may be filled with the solution even if a small amount of powder remains apparently undissolved. Although it may be more difficult for the patient to hold the solution, as compared with saline, he should retain it as long as possible. No irritation to the mucosa results and the bowel is cleansed more thoroughly than with ordinary solutions. This is particularly important when examination for some questionable structure is being undertaken, as the walls of the large intestine are left substantially cleaner than with other cleansers.

It must be remembered that if cultures are to be taken, these enemas should not be employed, for an absence of all microorganisms often results.

2) For impromptu bowel cleansing and sterilization:

Ligate or clamp above and below the portion to be resected.

Irrigate above and below the ligatures or clamps with 1,000 cc. of sterile normal saline followed by 500 cc. of 0.4 per cent solution. The colon can then be reclamped through the sterilized portion, the bowel divided, and resection and anastomosis carried out in the usual manner.

The solutions may be introduced with a 13 or 15 needle or small catheter through a sterile intravenous set and removed at the opposite end of the segment to be sterilized with a large catheter (#36 to #40) inserted through a colostomy opening with a purse string suture to prevent leakage. When the bowel is clamped for division the colostomy opening can be included with the specimen.

The usual contraindications to primary anastomosis should be observed as this method is designed only to overcome the factor of lack of preparation, or incomplete or inadequate preparation.

V. DERMATOLOGY

A. GENERAL

For this use, a concentration of 0.4 per cent Clorpactin WCS-90 (sodium oxychlorosene), is prepared. If the infected area can be immersed, the solution should be used as a bath for at least three minutes one to three times daily. Other areas can be treated with wet packs to which the solution is added three times daily or is supplied continuously by gravity.

DERMATOLOGIC INFECTIONS

For superficial infections, such as those occurring on skin grafts or where gangrene has set in, wet soaks of 0.4 per cent solution are used for several hours at a time, one to four times daily.⁽¹⁷⁾ For continuous treatment, additional fluid can be added to the dressing by gravity.

In a concentration of 0.2 per cent, the solution has been found helpful in controlling extensive purulent drainage associated with decubitus ulcers.⁽¹⁸⁾ The surrounding skin can be protected with zinc oxide ointment if necessary.

VI. OTOLARYNGOLOGY

Zwerling⁽¹⁹⁾ has reported beneficial results in 477 of 642 patients treated with Clorpactin WCS-90 (sodium oxychlorosene) in 0.2 per cent solution for the following conditions:

- Abscess, peritonsillar
- Carbuncle (neck)
- Cellulitis with perichondritis (ear)
- Dermatitis (skin of nasal vestibule)
- Fistula, oral-antral
- Furuncle of the nose
- Globus hystericus
- Herpes pharynx
- Mastoidectomy, complications
- Moniliasis (thrush)

Pharyngitis, acute
Pharyngitis, chronic
Pharyngitis with rhinitis (atrophic)
Rhinitis, acute
Rhinitis, chronic
Sinusitis, maxillary (acute)
Sinusitis, maxillary (chronic)
Stomatitis, aphthous
Stomatitis, catarrhal
Stomatitis, exanthematous
Stomatitis, secondary
Tonsillitis, acute
Tonsillitis, chronic
Uvulitis
Vincent's angina

Subsequently, this same investigator⁽²⁰⁾ reported good results in 181 additional cases of aphthous stomatitis.

VII. OPHTHALMOLOGY

A. OPHTHALMIC INFECTIONS

Gordon⁽²¹⁾ has found the 0.2 per cent solution useful in the treatment of 2 patients with severe chronic dacryocystitis and in 1 patient with bilateral corneal ulcer.

B. OPHTHALMIC USE

At the present time, Clorpactin WCS-90 (sodium oxychlorosene) should be used in the eye only for treatment of resistant infections and lacrimal sac irrigation. The solution of 0.2 per cent should be made as for instillation into the bladder and the excess discarded. Prior to ophthalmic instillation, the cornea should be anesthetized by instillation of several drops of an ophthalmic anesthetic.

VIII. OTHER SPECIFIC APPLICATIONS

A. IRRIGATION OF CHRONICALLY INFECTED SINUS TRACTS, FISTULAE, EMPYEMAS

For treating draining sinuses or fistulae, use a slow drip by gravity flow as the preferred form of treatment. From 5 to 10 cc. of 0.4 per cent solution per minute is a suitable rate. If the infection is severe, continue irrigation one to several hours per day, repeating irrigational procedure twice per day if necessary until cultures are negative and remain so for 72 hours.

B. OSTEOMYELITIS

When administered by gravity flow irrigation, the 0.4 per cent solution is valuable in the local treatment of chronic osteomyelitis. A suitable rate of flow is 5 to 10 cc. per minute.⁽¹⁷⁾

C. BURNS

The 0.1-0.2% solution is suggested for use in wet dressings for burns, primarily to prevent infection, especially by *Pseudomonas aeruginosa*. The activity of this solution against this organism has been reported independently by three different groups of investigators.^(6, 7, 11) Gauze packs placed gently on the burned area may be kept wet with the solution by means of gravity flow.

PREPARATION OF SOLUTION AND VARIATIONS IN CONCENTRATION

INTRODUCTION

Clorpactin WCS-90 is slow to dissolve in water. The organic hypochlorous acid complex is carried by an anhydrous hexametaphosphate base, which requires time to rehydrate after being placed in water.

However, the initial reaction with water releases the hypochlorous acid within 2 to 3 minutes of stirring. This is the active agent. The light, fluffy residue is actually the slowly rehydrating phosphates, which have no pharmacological value. On the other hand, this residue is harmless physiologically if incompletely dissolved.

DIRECTIONS

Add the powder to the required amount of cool or lukewarm water (not hot). Saline solution may be used where indicated. Stir or shake for a minute or two. Allow solution to stand for several minutes, then stir (or shake) for an additional 2 to 3 minutes. The solution may be used as such (disregarding any residue still left) or it may be allowed to settle for several minutes and the clear solution decanted for use.

This entire procedure should require no more than about 10 to 15 minutes, and the resultant solution has been shown to contain more than 95% of the active hypochlorous acid (based on the theoretical evaluation).

To endeavor to dissolve the product completely would require a much longer time and offer no advantages.

If the contents of a freshly opened 2 Gm. bottle of Clorpactin WCS-90 (sodium oxychlorosene) is added to:

Add to:	% Concentration
2000 ml.	0.1
1000 ml.	0.2
500 ml.	0.4
400 ml.	0.5
335 ml.	0.6

Surgical

- Burns, 0.1 % to 0.2 %
- Diabetic and Decubitus Ulcers, 0.2-0.4 %
- Infected Fistulae and Sinus Tracts, 0.4 %
- Impromptu Bowel Sterilization, 0.4 %
- Peritonitis, 0.4 %
- Preoperative Preparation, 0.4 %
- Skin Grafts, 0.2-0.4 %
- Surgical Irrigation, 0.4 %

Genito-Urinary

- Interstitial cystitis, tuberculous and non-tuberculous cystitis, initial instillation, 0.1 %, subsequent instillations, 0.2 %
- Indwelling catheter, 0.05-0.2 %
- Cervicitis, 0.4 %
- Vaginitis, 0.4 %

Ophthalmology

- Resistant Infections and Dacryocystitis, 0.2 %

Dermatology

- Aphthous stomatitis, 0.2 %
- Decubitus, Diabetic Ulcers, 0.2-0.4 %
- Infected Burns, 0.1-0.2 %
- Skin Grafts, 0.2-0.4 %

Proctology

- Amebiasis, 0.4 %
- Cleansing for examination, 0.4 %
- Colitis, 0.4 %
- Proctitis, 0.4 %
- Ulcerative Colitis, 0.4 %

Other Conditions

- Osteomyelitis, 0.4 %
- When wound is heavily contaminated with organic debris and drainage 0.5 % to 0.6 %

STABILITY OF THE SOLUTION

Clorpactin WCS-90 solutions will slowly lose their potency upon storage. The primary causes of the loss of potency are exposure to excessive heat and light. Below are the results of a study done on two strengths of Clorpactin WCS-90 solutions. The solutions were stored at room temperature (approx. 65° - 75° F.) in amber glass bottles which were capped during storage. The results are based on averages of the lots tested. We believe that these results are typical, and can provide a gauge of the expected drop in potency during storage. The product specification for a 0.1% solution is 60-80 p.p.m. available chlorine, and for a 0.2% solution is 120-160 p.p.m. Note that in both examples below the results fall just slightly under specification at 115 hours of storage (almost 5 days). Copies of our labelling in the past stated that the solutions should be discarded after 8-10 hours of storage. These results would indicate that the stability is much greater than originally stated. The results also indicate very slight stability differences between the two concentrations.

<u>Storage time</u>	<u>Available Cl-0.1% solution</u>	<u>Available Cl-0.2% solution</u>
1 hour	72.74 p.p.m.	145.95 p.p.m.
3 hours	72.12 p.p.m.	143.83 p.p.m.
19 hours	66.99 p.p.m.	134.32 p.p.m.
43 hours	67.37 p.p.m.	126.36 p.p.m.
115 hours	59.45 p.p.m.	116.10 p.p.m.

Additional studies were done on storage of Clorpactin WCS-90 solutions in plastic bottles. These results were very similar to those obtained above, therefore, stability in plastic bottles, capped, and at room temperature is the same as in glass. Storage of the solution under refrigeration will lengthen the stability to about 10 days. Storage away from light does not affect stability if an opaque or translucent container is used (amber glass or natural polyethylene) as opposed to a clear bottle.

SIDE EFFECTS AND CONTRAINDICATIONS

Clorpactin WCS-90 (sodium oxychlorosene) is not known to produce sensitivity, allergy, irritation or any evidence of toxicity when used in human beings in the recommended concentration. In some instances, instillation of the 0.2 per cent solution, particularly into the bladder or into the eye, may cause sever discomfort. This is avoided in the eye by pre-treatment with a topical anesthetic and in the bladder by using a concentration of only 0.1 percent for the first treatment, instilling the solution to the capacity of the bladder without over-distention.

Pathogenic organisms do not become resistant to this agent because the oxidizing power of Clorpactin causes the lysing of the organism.

However, it is suitable *only* for use in the treatment or prevention of infections which can be reached by one of the methods of topical application described in the previous section. It is *contraindicated* for systemic administration for the treatment of systemic infections. Inability to reach the infected area directly with the solution is a *contraindication* to the use of Clorpactin WCS-90.

CAUTION: Clorpactin should *never* be used as a powder. The strong oxidizing power of the powder will cause burns that can result in necrotic tissue. It should be used as a solution only, of the types, and in the concentrations, specified.

HOW SUPPLIED:

IN BOXES, EACH CONTAINING 5 TWO GRAM BOTTLES OF
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