

1.3.1.1 Package Insert

1 SCHEDULING STATUS

2

S1

3 PROPRIETARY NAME AND DOSAGE FORM

4 VIVIDRIN EYE DROPS.

5 COMPOSITION

6 Each ml contains: Sodium Cromoglycate 20 mg

7 Preservative: Benzalkonium Chloride 0,01 % *m/v* in a sterile solution.

8 Other excipients include disodium edetate, polysorbate 80, sorbitol and water for injection.

9 PHARMACOLOGICAL CLASSIFICATION

10 A 15.4 Ophthalmic Preparations – Other

11 INDICATIONS

12 Allergic conjunctivitis.

13 CONTRAINDICATIONS

14 Hypersensitivity to ingredients.

15 WARNINGS AND SPECIAL PRECAUTIONS

16 Safety in pregnancy has not been established. Where concomitant steroid and sodium
17 cromoglycate treatment has rendered it possible to reduce the steroid dose, precautions
18 must be taken to prevent a severe attack if/when sodium cromoglycate is withdrawn from
19 treatment regime.

20 As the possibility of adverse effects on the corneal permeability and the danger of disruption
21 of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride
22 preserved Ophthalmological preparations cannot be excluded, regular ophthalmological
23 examination is required. Caution should be exercised in the use of benzalkonium chloride
24 preserved topical medication over an extended period in patients with extensive ocular
25 surface disease.

26 **DOSAGE AND DIRECTIONS FOR USE**

27 For adults and children: 1-2 drops into each eye 4 times daily.

28 Since therapy with sodium cromoglycate is essentially prophylactic, it is important to instruct
29 patients to maintain regular dosage.

30 **SIDE EFFECTS**

31 Soft contact lenses should not be worn during treatment as they may be affected by the
32 benzalkonium chloride (preservative). Side effects in hypersensitive persons may include
33 headache, skin rash, bronchospasm, breathlessness, anaphylaxis.

34 **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

35 If a hypersensitive reaction occurs, withdraw treatment.

36 **IDENTIFICATION**

37 A clear, non-viscous, slightly yellow solution.

38 **PRESENTATION**

39 White plastic bottle containing 10 ml of solution. Tamper-proof white cap.

40 **STORAGE INSTRUCTIONS**

41 Store at or below 25 °C. Discard 30 days after opening.

42 KEEP OUT OF REACH OF CHILDREN.

43 **REGISTRATION NUMBER**

44 W/15.4/86

45 **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**
46 **REGISTRATION**

47 Soflens (Pty) Ltd

48 254 Hall Street

49 Centurion

50 01157

51 **DATE OF PUBLICATION OF THIS PACKAGE INSERT**

52 08/05/1989