

Amendment date: 12 April 2019

1 **1.3.1.1 Package Insert (clean)**

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3 **SCHEDULING STATUS**

4 S0

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6 **PROPRIETARY NAME AND DOSAGE FORM**

7 **Legalon® 70 Tablets**

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9 **COMPOSITION**

10 Each tablet contains 70 mg silymarin

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12 **PHARMACOLOGICAL CLASSIFICATION**

13 A 7.4 (Lipotropic agents)

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15 **PHARMACOLOGICAL ACTION**

16 In animal experiments, silymarin (of plant origin) has been shown to exert an anti-
17 hepatotoxic action against various liver cell toxins.

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19 It is postulated that the anti-hepatotoxic action may be due to a membrane-stabilizing
20 effect and/or stimulation of RNA-synthesis.

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22 **INDICATIONS**

23 A healthy aid to support liver function

24 Assist in the regeneration of liver cell membrane

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25 As an aid in the treatment of alcohol-induced liver disease

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27 **CONTRA-INDICATIONS**

28 Hypersensitivity to silymarin

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30 **PREGNANCY AND LACTATION**

31 Hypersensitivity to silymarin

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33 **DOSAGE AND DIRECTIONS FOR USE**

34 Take two tablets three times daily.

35 As a maintenance dose take one tablet three times daily.

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37 **SIDE EFFECTS AND SPECIAL PRECAUTIONS**

38 No side effects have been reported

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40 **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS**

41 **TREATMENT**

42 In the event of any adverse reaction occurring, consult a medical practitioner or the
43 nearest hospital. Treatment is symptomatic and supportive.

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45 **IDENTIFICATION**

46 Brown sugar-coated tablets

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49 **PRESENTATION**

50 Available in blister packs of 20, 40 and 100 sugar-coated tablets

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52 **STORAGE INSTRUCTIONS**

53 Store below 25 °C. Keep out of reach of children

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55 **REFERENCE NUMBER**

56 R/7.4/172

57

58 **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE REGISTRATION**

59 **CERTIFICATE**

60 XIXIA PHARMACEUTICALS (PTY) LTD

61 Building 6

62 Greenstone Hill Office Park

63 Emerald Boulevard

64 Modderfontein

65 1645

66

67 **DATE OF PUBLICATION OF THE PACKAGE INSERT**

68 11 December 1990

69 (Revision: 31st Jan 2018)