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| 1.  | <b>ANNOTATED AMENDED PROPOSED PATIENT INFORMATION</b>   | All section headings amended (added, moved or deleted) as per General Regulations as amended 25 August 2017 and SAHPRA Guideline for Patient Information Leaflet for Human Medicines, July 2019 (changes applicable throughout document). |
| 2.  | <b>LEAFLET</b>  |   |
| 3.  |   |   |
| 4.  | <b>SCHEDULING STATUS: S4</b>  |   |
| 5.  |   |   |
| 6.  | <b>PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM</b>   |   |
| 7.  | <b>[PRODUCT NAME] 25 Film-coated tablets</b>  |   |
| 8.  | <b>[PRODUCT NAME] 50 Film-coated tablets</b>  |   |
| 9.  | <b>[PRODUCT NAME] 100 Film-coated tablets</b>   |   |
| 10. | <b><u>Sildenafil citrate</u></b>  |   |
| 11. | <b><u>Sugar free</u></b>  |   |
| 12. |   |   |
| 13. | <b>Read all of this leaflet carefully before you start taking [PRODUCT NAME]</b>  |   |
| 14. | <ul style="list-style-type: none"> <li>Keep this leaflet. You may need to read it again.</li> </ul>                               |   |
| 15. | <ul style="list-style-type: none"> <li>If you have further questions, please ask your doctor, <u>pharmacist, nurse</u></li> </ul> |   |
| 16. | <ul style="list-style-type: none"> <li>or <del>your pharmacist</del> <u>other health care provider.</u></li> </ul>                |   |
| 17. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] has been prescribed for you personally and you</li> </ul>                   |   |
| 18. | <ul style="list-style-type: none"> <li>should not share your medicine with other people. It may harm them,</li> </ul>             |   |
| 19. | <ul style="list-style-type: none"> <li>even if their symptoms are the same as yours.</li> </ul>                                   |   |
| 20. |   |   |
| 21. | <b><u>What is in this leaflet</u></b>   |   |
| 22. | <u>1. What [PRODUCT NAME] is and what it is used for</u>  |   |
| 23. | <u>2. What you need to know before you take [PRODUCT NAME]</u>  |   |
| 24. | <u>3. How to take [PRODUCT NAME]</u>  |   |

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| 25. | <u>4. Possible side effects</u>   |                     |
| 26. | <u>5. How to store [PRODUCT NAME]</u>   |                     |
| 27. | <u>6. Contents of the pack and other information</u>  |                     |
| 28. |   |                     |
| 29. | <b>4. What [PRODUCT NAME] contains</b>  | Moved to section 6. |
| 30. | The active ingredient present in [PRODUCT NAME] tablets is sildenafil.  |                     |
| 31. | <del>[PRODUCT NAME] 25: Each film-coated tablet contains sildenafil citrate</del>   |                     |
| 32. | <del>equivalent to sildenafil 25 mg.</del>  |                     |
| 33. | <del>[PRODUCT NAME] 50: Each film-coated tablet contains sildenafil citrate</del>   |                     |
| 34. | <del>equivalent to sildenafil 50 mg.</del>  |                     |
| 35. | <del>[PRODUCT NAME] 100: Each film-coated tablet contains sildenafil citrate</del>  |                     |
| 36. | <del>equivalent to sildenafil 100 mg.</del>   |                     |
| 37. | <del>[PRODUCT NAME] contains the following inactive ingredients: Anhydrous</del>  |                     |
| 38. | <del>calcium hydrogen phosphate, croscarmellose sodium, magnesium</del>   |                     |
| 39. | <del>stearate, microcrystalline cellulose and Opadry red (film coating material).</del>   |                     |
| 40. |   |                     |
| 41. | <b><u>2.1. What [PRODUCT NAME] is and what it is used for</u></b>   |                     |
| 42. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] contain sildenafil, which belongs to a group of medicines called phosphodiesterase type 5 inhibitors. It works by relaxing the blood vessels in your penis when you are sexually excited. This allows blood to flow into your penis, allowing you to get an erection in the natural way.</li> </ul> |                     |
| 43. |   |                     |
| 44. |   |                     |
| 45. |   |                     |
| 46. |   |                     |
| 47. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] is used to treat erectile dysfunction, more known as impotence, in men. This is when a man cannot get, or keep, a hard erect penis suitable for sexual activity.</li> </ul>   |                     |
| 48. |   |                     |
| 49. |   |                     |
| 50. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] will work only if you are sexually excited.</li> </ul>  |                     |
| 51. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] will not increase your sex drive.</li> </ul>  |                     |
| 52. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] is not for use in women.</li> </ul>   |                     |
| 53. | <ul style="list-style-type: none"> <li>[PRODUCT NAME] is not indicated for use by children.</li> </ul>  |                     |

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| 54. |   |  |
| 55. | <b><u>3.2. What you need to know before you take [PRODUCT NAME]</u></b>   |  |
| 56. | <b>Do not take [PRODUCT NAME]:</b>  |  |
| 57. | <ul style="list-style-type: none"> <li>If you are <del>allergic (hypersensitive)</del> hypersensitive (allergic) to sildenafil</li> </ul> |  |
| 58. | or any of the other ingredients of [PRODUCT NAME] (listed in section 6).  |  |
| 59. | <ul style="list-style-type: none"> <li>If you are taking medicines called nitrates and nitric oxide donors, as</li> </ul>                 |  |
| 60. | the combination may cause a potentially dangerous decrease in your  |  |
| 61. | blood pressure. Tell your doctor if you are taking any of these   |  |
| 62. | medicines which are often given for relief of angina pectoris (or ‘chest  |  |
| 63. | pain’). If you are not certain, ask your doctor or pharmacist.  |  |
| 64. | <ul style="list-style-type: none"> <li><u>If you are using cimetidine (used to treat ulcers), ketoconazole or</u></li> </ul>              | Amended PI, Section 4.3, page 7, lines 164-165 |
| 65. | <u>itraconazole (used to treat fungal infections), erythromycin or</u>  |  |
| 66. | <u>rifampicin (used to treat infections) or ritonavir or saquinavir (used to</u>  |  |
| 67. | <u>treat HIV infections).</u>   |  |
| 68. | <ul style="list-style-type: none"> <li>If you have a severe heart, kidney or liver problems.</li> </ul>                                   |  |
| 69. | If you think any of these apply to you, do not take [PRODUCT NAME], talk  |  |
| 70. | to your doctor and follow the advice given.   |  |
| 71. | <b><u>Take special care with [PRODUCT NAME]: Warnings and precautions</u></b>   |  |
| 72. | <b><u>If you have any of the following condition/illness: Take special care</u></b>   |  |
| 73. | <b><u>with [PRODUCT NAME]:</u></b>  |  |
| 74. | <ul style="list-style-type: none"> <li>If you have sickle cell anaemia (an abnormality of red blood cells),</li> </ul>                    |  |
| 75. | leukaemia (cancer of blood cells), multiple myeloma (cancer of bone   |  |
| 76. | marrow).  |  |
| 77. | <ul style="list-style-type: none"> <li>If you have a deformity of your penis or any other problem with your</li> </ul>                    |  |
| 78. | penis.  |  |
| 79. | <ul style="list-style-type: none"> <li>If you have an erection which lasts for more than 4 hours, you should</li> </ul>                   |  |
| 80. | contact a doctor immediately.   |  |

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| 81.  | <ul style="list-style-type: none"> <li>If you have problems with your heart. Your doctor will determine if your heart is healthy enough to handle the extra strain of having sex.</li> </ul>                          |  |
| 82.  |   |  |
| 83.  | <ul style="list-style-type: none"> <li>If you have recently had a stroke or a heart attack, or if you have any disorder of your heart rate or rhythm (such as beating too fast, too slow, or irregularly).</li> </ul> |  |
| 84.  |   |  |
| 85.  |   |  |
| 86.  | <ul style="list-style-type: none"> <li>If you have very low or very high blood pressure.</li> </ul>   |  |
| 87.  | <ul style="list-style-type: none"> <li>If you have certain rare inherited eye diseases (such as retinitis pigmentosa).</li> </ul>   |  |
| 88.  |   |  |
| 89.  | <ul style="list-style-type: none"> <li>If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).</li> </ul>   |  |
| 90.  |   |  |
| 91.  | <ul style="list-style-type: none"> <li>If you are taking any other oral or local treatments for erectile dysfunction.</li> </ul>  |  |
| 92.  |   |  |
| 93.  | <ul style="list-style-type: none"> <li>If you have stomach ulcers or any types of bleeding problems.</li> </ul>   |  |
| 94.  | <ul style="list-style-type: none"> <li>If you are over 65 years.</li> </ul>   |  |
| 95.  | <ul style="list-style-type: none"> <li>If you have a sudden hearing problem in one or both ears</li> </ul>  | Amended PI, section 4.4, page 10, lines 252-257. |
| 96.  |   |  |
| 97.  | <del>Take</del> <b>Other medicines with and [PRODUCT NAME]</b>  | Moved from below.                                |
| 98.  | <del>Always tell your health care professional if you are taking any other</del>  |  |
| 99.  | <del>medicine. (This includes all complementary or traditional medicines.)</del>  |  |
| 100. | <del>Remember to tell your doctor about your treatment with [PRODUCT</del>  |  |
| 101. | <del>NAME] tablets if you are prescribed another medicine while the treatment</del>   |  |
| 102. | <del>is still ongoing. This is especially important, if you are taking any medicines:</del>   |  |
| 103. | <del>[PRODUCT NAME] tablets may interfere with some medicines, especially</del>   |  |
| 104. | <del>those used to treat chest pain. In the event of a medical emergency, you</del>   |  |
| 105. | <del>should tell any healthcare professional treating your condition that you</del>   |  |
| 106. | <del>have taken [PRODUCT NAME] tablets and when you did. Do not take</del>  |  |
| 107. | <del>sildenafil. [PRODUCT NAME] tablets with other medicines unless your</del>  |  |
|      | <del>doctor tells you that you can.</del>   |  |
| 108. | <del>Especially tell your doctor if you are taking:</del>   |  |

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| 109. | <ul style="list-style-type: none"> <li>Medicines called nitrates (used for relief of angina pectoris/ 'chest pain'), as the combination of these medicines with [PRODUCT NAME] may lead to a dangerous fall in your blood pressure.</li> </ul>   |  |
| 110. |  |  |
| 111. |  |  |
| 112. | <ul style="list-style-type: none"> <li>Medicines known as nitric oxide donors, such as amyl nitrate ('poppers'), as the combination with [PRODUCT NAME] may also lead to a dangerous fall in your blood pressure.</li> </ul>   |  |
| 113. |  |  |
| 114. |  |  |
| 115. | <ul style="list-style-type: none"> <li>Cimetidine, a medicine used to treat ulcers.</li> </ul>   |  |
| 116. | <ul style="list-style-type: none"> <li>Some medicines used to treat fungal infections including ketoconazole and itraconazole.</li> </ul>  |  |
| 117. |  |  |
| 118. | <ul style="list-style-type: none"> <li>Some antibiotics including erythromycin.</li> </ul>   |  |
| 119. | <ul style="list-style-type: none"> <li>Some medicines used to treat HIV such as saquinavir or ritonavir.</li> </ul>  |  |
| 120. | <ul style="list-style-type: none"> <li>Medicines called alpha-blockers (such as doxazosin, silodosin, prazosin, tamsulosin, alfuzosin and terazosin). These are used treat high blood pressure or prostate problems. Some patients may experience dizziness and light-headedness (which may be caused by low blood pressure upon sitting or standing up quickly) when taking [PRODUCT NAME] with alpha-blockers. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start [PRODUCT NAME]. Your doctor may start you on a lower dose of [PRODUCT NAME].</li> </ul> |  |
| 121. |  |  |
| 122. |  |  |
| 123. |  |  |
| 124. |  |  |
| 125. |  |  |
| 126. |  |  |
| 127. |  |  |
| 128. |  |  |
| 129. |  |  |
| 130. | <b>Taking [PRODUCT NAME] with food, and drink and alcohol</b>  |  |
| 131. | <p>[PRODUCT NAME] can be taken with or without food. However, you may find that [PRODUCT NAME] takes longer to start working if you take it with a heavy meal.</p>   |  |
| 132. |  |  |
| 133. | <p>Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from [PRODUCT NAME], you are advised not to drink excessive amounts of alcohol before taking [PRODUCT NAME].</p>  |  |
| 134. |  |  |
| 135. |  |  |
| 136. | <b>Pregnancy, and breastfeeding and fertility</b>  |  |

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|------|---|--------------|
| 137. | <u>If you are pregnant or breastfeeding your baby, think you may be pregnant</u>            |              |
| 138. | <u>or are planning to have a baby, please consult your doctor, pharmacist or</u>            |              |
| 139. | <u>other health care provider for advice before taking this medicine.</u>                   |              |
| 140. | [PRODUCT NAME] is not indicated for use by women.   |              |
| 141. | <b>Driving and using machines</b>   |              |
| 142. | <u>It is not always possible to predict to what extent [PRODUCT NAME] may</u>               |              |
| 143. | <u>interfere with the daily activities of a patient. Patients should ensure that</u>        |              |
| 144. | <u>they do not engage in the above activities until they are aware of the</u>               |              |
| 145. | <u>measure to which [PRODUCT NAME] affects them.</u>  |              |
| 146. | [PRODUCT NAME] can cause dizziness and can affect vision. You should                        |              |
| 147. | be aware of how you react to [PRODUCT NAME] before you drive or use                         |              |
|      | machinery.  |              |
| 148. | <b>Taking other medicines with [PRODUCT NAME]</b>   | Moved above. |
| 149. | <del>Always tell your healthcare professional if you are taking any other</del>             |              |
| 150. | <del>medicine. (This includes complementary or traditional medicines.)</del>                |              |
| 151. | <del>Remember to tell your doctor about your treatment with [PRODUCT</del>                  |              |
| 152. | <del>NAME] tablets if you are prescribed another medicine while the treatment</del>         |              |
| 153. | <del>is still ongoing. This is especially important, if you are taking any medicines:</del> |              |
| 154. | <del>[PRODUCT NAME] tablets may interfere with some medicines, especially</del>             |              |
| 155. | <del>those used to treat chest pain. In the event of a medical emergency, you</del>         |              |
| 156. | <del>should tell any healthcare professional treating your condition that you</del>         |              |
| 157. | <del>have taken [PRODUCT NAME] tablets and when you did. Do not take</del>                  |              |
| 158. | <del>sildenafil tablets with other medicines unless your doctor tells you that you</del>    |              |
|      | <del>can.</del>   |              |
| 159. | Especially tell your doctor if you are taking:  |              |
| 160. | • <del>Medicines called nitrates (used for relief of angina pectoris/ 'chest</del>          |              |
| 161. | <del>pain'), as the combination of these medicines with [PRODUCT NAME]</del>                |              |
| 162. | <del>may lead to a dangerous fall in your blood pressure.</del>                             |              |

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| 163. | <ul style="list-style-type: none"> <li>Medicines known as nitric oxide donors, such as amyl nitrate ('poppers'), as the combination with [PRODUCT NAME] may also lead to a dangerous fall in your blood pressure.</li> </ul>   |  |
| 164. |  |  |
| 165. |  |  |
| 166. |  |  |
| 167. |  |  |
| 168. | <ul style="list-style-type: none"> <li>Cimetidine, a medicine used to treat ulcers.</li> </ul>   |  |
| 169. | <ul style="list-style-type: none"> <li>Some medicines used to treat fungal infections including ketoconazole and itraconazole.</li> </ul>  |  |
| 170. | <ul style="list-style-type: none"> <li>Some antibiotics including erythromycin.</li> </ul>   |  |
| 171. | <ul style="list-style-type: none"> <li>Some medicines used to treat HIV such as saquinavir or ritonavir.</li> </ul>  |  |
| 172. | <ul style="list-style-type: none"> <li>Medicines called alpha-blockers (such as doxazosin, silodosin, prazosin, tamsulosin, alfuzosin and terazosin). These are used treat high blood pressure or prostate problems. Some patients may experience dizziness and light headedness (which may be caused by low blood pressure upon sitting or standing up quickly) when taking [PRODUCT NAME] with alpha-blockers. To reduce the chance that these symptoms might happen, you should be on a regular daily dose of your alpha-blocker before you start [PRODUCT NAME]. Your doctor may start you on a lower dose of [PRODUCT NAME].</li> </ul> |  |
| 173. |  |  |
| 174. |  |  |
| 175. |  |  |
| 176. |  |  |
| 177. |  |  |
| 178. |  |  |
| 179. |  |  |
| 180. |  |  |
| 181. | <b>4.3. How to take [PRODUCT NAME]</b>   |  |
| 182. | Do not share medicines prescribed for you with any other person.   |  |
| 183. | <p>Always take [PRODUCT NAME] exactly as your doctor or pharmacist has instructed <u>told</u> you. You should <u>e</u>Check with your doctor or pharmacist if you are <u>unsure-not</u> sure.</p>  |  |
| 184. |  |  |
| 185. |  |  |
| 186. | <p>The usual starting dose is 50 mg, however based on your condition, a lower starting dose (i.e. 25 mg) may be recommended by your doctor.</p>  |  |
| 187. |  |  |
| 188. | <p>[PRODUCT NAME] is to be taken about one hour before you plan to have sex.</p>   |  |
| 189. | <p>Based upon your response your doctor may increase your dose to 100 mg or decrease the dose to 25 mg. The maximum daily dose is 100 mg.</p>  |  |
| 190. |  |  |

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd  
 Sildenafil 25 mg/ 50 mg/ 100 mg film-coated tablets  
 Dosage form: Film-coated tablets

Strength: Each film-coated tablet contains sildenafil citrate equivalent to sildenafil 25 mg/ 50 mg/ 100 mg

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| 191. | <del>You should swallow the tablet(s) whole, with water.</del> <u>Take the tablets with a</u> |  |
| 192. | <u>sufficient quantity of liquid (e.g. one glass of water).</u>                               |  |
| 193. | <u>Do not chew.</u>   |  |
| 194. | You should not take [PRODUCT NAME] more than once a day.                                      |  |
| 195. | <u>Your doctor will tell you how long your treatment with [PRODUCT NAME]</u>                  |  |
| 196. | <u>will last.</u> If you have the impression that the effect of [PRODUCT NAME] is             |  |
| 197. | too strong or too weak, <del>talk to</del> <u>tell</u> your doctor or pharmacist.             |  |
| 198. | If [PRODUCT NAME] does not help you to get an erection, or if your                            |  |
| 199. | erection does not last long enough for you to complete sexual intercourse                     |  |
| 200. | you should tell your doctor.  |  |
| 201. | <b><u>If you take more [PRODUCT NAME] than you should</u></b>                                 |  |
| 202. | <del>In the event of overdosage, consult your doctor or pharmacist. If neither is</del>       |  |
| 203. | <del>available, contact the nearest hospital or poison control centre.</del>                  |  |
| 204. | You may experience an increase in side effects and their severity. Doses                      |  |
| 205. | above 100 mg do not increase the efficacy. You should not take more                           |  |
| 206. | tablets than your doctor tells you to.  |  |
| 207. | <del>In the event of overdosage, consult your doctor or pharmacist. If neither is</del>       |  |
| 208. | <del>available, contact the nearest hospital or poison control centre.</del>                  |  |
| 209. | Take along any tablets that are left, the container and the label so that the                 |  |
| 210. | hospital will know what you have taken.   |  |
| 211. | If you have any further questions on the use of [PRODUCT NAME], ask                           |  |
| 212. | your doctor or pharmacist.  |  |
| 213. | <b><u>If you forget to take [PRODUCT NAME]</u></b>  |  |
| 214. | <u>Do not take / receive a double dose to make up for forgotten individual</u>                |  |
| 215. | <u>doses.</u>   |  |
| 216. |   |  |
| 217. | <b><u>5.4. Possible side effects</u></b>  |  |
| 218. | [PRODUCT NAME] can have side effects.   |  |

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| 219. | Not all side effects reported for [PRODUCT NAME] are included in this                |  |
| 220. | leaflet. Should your general health worsen or if you experience any                  |  |
| 221. | untoward effects while taking [PRODUCT NAME], please consult your                    |  |
| 222. | <del>doctor, pharmacist or other health care professional provider</del> for advice. |  |
| 223. | <b><i>Very serious side effects</i></b>  |  |
| 224. | If any of the following happens, stop taking [PRODUCT NAME] and tell                 |  |
| 225. | your doctor immediately or go to the casualty department at your nearest             |  |
|      | hospital:  |  |
| 226. | • Sudden wheeziness, shortness of breath, difficulty in breathing, chest             |  |
| 227. | constriction, swelling of the eyelids, face, lips or throat, rashes, hives,          |  |
| 228. | itching, or high temperature.  |  |
| 229. | These are <u>all</u> very serious side effects. If you have them, you may have       |  |
| 230. | had a serious allergic reaction to <del>the components of</del> [PRODUCT NAME].      |  |
| 231. | You may need urgent medical attention or hospitalisation.                            |  |
| 232. | <b><i>Serious side effects</i></b>   |  |
| 233. | Tell your doctor <u>immediately</u> or go to the casualty department at your         |  |
| 234. | nearest hospital if you notice any of the following:                                 |  |
| 235. | • Eye bleeding.  |  |
| 236. | • Blood in urine.  |  |
| 237. | • Shock.   |  |
| 238. | • Heart attack.  |  |
| 239. | • Chest pain.  |  |
| 240. | These are all serious side effects. You may need urgent medical attention.           |  |
| 241. | If you have chest pains during or after intercourse:                                 |  |
| 242. | • Get in a semi-sitting position and try to relax.                                   |  |
| 243. | • <b>Do not use nitrates</b> to treat your chest pain.                               |  |
| 244. | • Contact your doctor immediately.   |  |
| 245. | If you experience a sudden decrease or loss of vision, stop taking                   |  |
| 246. | [PRODUCT NAME] and contact your doctor immediately.                                  |  |

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| 247. | <b><del>Other side effects</del></b>   |  |
| 248. | Tell your doctor <del>or pharmacist</del> if you notice any of the following:  |  |
| 249. | <u>Frequent side effects:</u>  |  |
| 250. | <ul style="list-style-type: none"> <li>Headache, flushing, dizziness.</li> </ul>                                       |  |
| 251. | <ul style="list-style-type: none"> <li>Abnormal vision (predominantly colour tinge to vision, but also</li> </ul>      |  |
| 252. | <ul style="list-style-type: none"> <li>increased perception of light or blurred vision).</li> </ul>                    |  |
| 253. | <ul style="list-style-type: none"> <li>Fast and irregular heartbeats.</li> </ul>                                       |  |
| 254. | <ul style="list-style-type: none"> <li>Nasal congestion.</li> </ul>  |  |
| 255. | <ul style="list-style-type: none"> <li>Indigestion.</li> </ul>   |  |
| 256. | <u>Less frequent side effects or frequency unknown:</u>  |  |
| 257. | <ul style="list-style-type: none"> <li>Sensitivity to sunlight (photophobia).</li> </ul>                               |  |
| 258. | <ul style="list-style-type: none"> <li>Double vision, temporary loss of vision/ decreased vision, cataract.</li> </ul> |  |
| 259. | <ul style="list-style-type: none"> <li>Red eyes, burning eyes, abnormal sensation in the eye, dry eyes and</li> </ul>  |  |
| 260. | <ul style="list-style-type: none"> <li>eye pain.</li> </ul>  |  |
| 261. | <ul style="list-style-type: none"> <li>Painful erection (priapism).</li> </ul>   |  |
| 262. | <ul style="list-style-type: none"> <li>Night time urination, increased urination.</li> </ul>                           |  |
| 263. | <ul style="list-style-type: none"> <li>Breast enlargement.</li> </ul>  |  |
| 264. | <ul style="list-style-type: none"> <li>Unable to hold urine, abnormal ejaculation, swelling of penis.</li> </ul>       |  |
| 265. | <ul style="list-style-type: none"> <li>Accidental injury.</li> </ul>   |  |
| 266. | <ul style="list-style-type: none"> <li>Inflammation which causes abdominal pain and diarrhoea.</li> </ul>              |  |
| 267. | <ul style="list-style-type: none"> <li>Difficulty in swallowing (dysphagia).</li> </ul>                                |  |
| 268. | <ul style="list-style-type: none"> <li>Pain in upper abdomen that may become either worse or better</li> </ul>         |  |
| 269. | <ul style="list-style-type: none"> <li>(gastritis).</li> </ul>   |  |
| 270. | <ul style="list-style-type: none"> <li>Rectal bleeding.</li> </ul>   |  |
| 271. | <ul style="list-style-type: none"> <li>Reduction in red blood cells which makes the skin pale and cause</li> </ul>     |  |
| 272. | <ul style="list-style-type: none"> <li>weakness and breathlessness, persistent sore throat and frequent</li> </ul>     |  |
| 273. | <ul style="list-style-type: none"> <li>infections.</li> </ul>  |  |
| 274. | <ul style="list-style-type: none"> <li>Low sugar levels in the blood (hypoglycaemia) presenting with</li> </ul>        |  |
| 275. | <ul style="list-style-type: none"> <li>sweating.</li> </ul>  |  |

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| 276. | <ul style="list-style-type: none"> <li>Decreased motor function such as hand eye co-ordination (hypoglycaemic reaction).</li> </ul>  |  |
| 277. |  |  |
| 278. | <ul style="list-style-type: none"> <li>High levels of sodium in the blood manifested as loss of appetite, restlessness, nausea, and vomiting (hypernatraemia).</li> </ul>  |  |
| 279. |  |  |
| 280. | <ul style="list-style-type: none"> <li>Tendon rupture.</li> </ul>  |  |
| 281. | <ul style="list-style-type: none"> <li>Swelling and difficulty moving the particular joint where the inflammation occurs (tenosynovitis).</li> </ul>   |  |
| 282. |  |  |
| 283. | <ul style="list-style-type: none"> <li>Muscles becoming progressively weaker during periods of activity and improve after rest (myasthenia gravis).</li> </ul>   |  |
| 284. |  |  |
| 285. | <ul style="list-style-type: none"> <li>Lack of coordination of muscle movements.</li> </ul>  |  |
| 286. | <ul style="list-style-type: none"> <li>Spinning sensation.</li> </ul>  |  |
| 287. | <ul style="list-style-type: none"> <li>Depression.</li> </ul>  |  |
| 288. | <ul style="list-style-type: none"> <li>Asthma, shortness of breath.</li> </ul>   |  |
| 289. | <ul style="list-style-type: none"> <li>Inflammation of the air passages within the lungs manifested by cough (bronchitis).</li> </ul>  |  |
| 290. |  |  |
| 291. | <ul style="list-style-type: none"> <li>Shingles (herpes simplex), skin ulcer, scaling of skin (exfoliative dermatitis).</li> </ul>   |  |
| 292. |  |  |
| 293. | <ul style="list-style-type: none"> <li>High blood pressure, low blood pressure.</li> </ul>   |  |
| 294. | <ul style="list-style-type: none"> <li>Migraine.</li> </ul>  |  |
| 295. | <ul style="list-style-type: none"> <li>Fainting.</li> </ul>  |  |
| 296. | <ul style="list-style-type: none"> <li>Dizziness upon sudden standing up (postural hypotension).</li> </ul>  |  |
| 297. | <ul style="list-style-type: none"> <li>Feeling of weakness, pain, chills.</li> </ul>   |  |
| 298. | <ul style="list-style-type: none"> <li>Accidental fall.</li> </ul>   |  |
| 299. | <ul style="list-style-type: none"> <li>Inflammation or irritation of mucous lining of the tongue (glossitis) or swallowing tube leading to the stomach (oesophagitis) or cheeks, gums, tongue, lips, throat (stomatitis).</li> </ul> |  |
| 300. |  |  |
| 301. |  |  |
| 302. | <ul style="list-style-type: none"> <li>Abdominal pain, loose motions, nausea and vomiting (being sick).</li> </ul>   |  |
| 303. | <ul style="list-style-type: none"> <li>Dry mouth, abnormal test results of the liver.</li> </ul>   |  |
| 304. | <ul style="list-style-type: none"> <li>Thirst.</li> </ul>  |  |

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|------|--|--|
| 305. | • Swelling (oedema).   |  |
| 306. | • Painful joints, joint swelling.  |  |
| 307. | • Muscle pain, bone pain.  |  |
| 308. | • Increased muscle tone.   |  |
| 309. | • Severe nerve pain, weakness tingling and numbness (neuropathy).  |  |
| 310. | • Tingling or numbness of the hands or feet (paraesthesia).  |  |
| 311. | • Tremor.  |  |
| 312. | • Insomnia, feeling sleepy, abnormal dreams.   |  |
| 313. | • Reflexes decreased.  |  |
| 314. | • Increased perception to pain.  |  |
| 315. | • Inflammation of the larynx (voice box) causing hoarseness voice or the   |  |
| 316. | complete loss of the voice (laryngitis).   |  |
| 317. | • Sore throat (pharyngitis).   |  |
| 318. | • Sinusitis.   |  |
| 319. | • Increased sputum, increased cough.   |  |
| 320. | • Sweating.  |  |
| 321. | • Localised rash or irritation of the skin (contact dermatitis).   |  |
| 322. | • Ringing in the ears (tinnitus), deafness, ear pain.  |  |
| 323. | If you notice any side effects not mentioned in this leaflet, please inform  |  |
| 324. | your doctor or pharmacist.   |  |
| 325. | <b><u>Reporting of side effects</u></b>  |  |
| 326. | <u>If you get side effects, talk to your doctor, pharmacist or nurse. You can</u>  |  |
| 327. | <u>also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction</u>  |  |
| 328. | <u>Reporting Form”, found online under SAHPRA’s publications:</u>  |  |
| 329. | <u><a href="https://www.sahpra.org.za/Publications/Index/8">https://www.sahpra.org.za/Publications/Index/8</a>. By reporting side effects,</u> |  |
| 330. | <u>you can help provide more information on the safety of [PRODUCT NAME].</u>  |  |
| 331. |  |  |
| 332. | <b><u>6. STORAGE AND DISPOSING OF [PRODUCT NAME]</u></b>   |  |
| 333. | <b><u>5. How to store [PRODUCT NAME]</u></b>   |  |

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd  
 Sildenafil 25 mg/ 50 mg/ 100 mg film-coated tablets  
 Dosage form: Film-coated tablets

Strength: Each film-coated tablet contains sildenafil citrate equivalent to sildenafil 25 mg/ 50 mg/ 100 mg

|      |   |                                |
|------|---|--------------------------------|
| 334. | <del>Keep out of the reach and sight of children.</del> <u>Store all medicines out of reach</u>       | Moved from below and reworded. |
| 335. | <u>of children.</u>   |                                |
| 336. | • <u>Store at or below 30 °C.</u>   |                                |
| 337. | • <u>Store in the original package/ container.</u>  |                                |
| 338. | • <del>Keep the blisters should be kept</del> <u>in the outer carton until required for</u>           |                                |
| 339. | <u>use.</u>   |                                |
| 340. | • <u>Protect from light / moisture.</u>   |                                |
| 341. | • <u>Do not store in a bathroom.</u>  |                                |
| 342. | • Do not take <del>[PRODUCT NAME]</del> <u>use</u> after the expiry date stated on the                |                                |
| 343. | <u>pack carton.</u> <del>The expiry date refers to the last day of that month.</del>                  |                                |
| 344. | • <u>Return all unused medicine to your pharmacist.</u>   |                                |
| 345. | <del>Medicines should not be disposed of via wastewater or household waste.</del>                     |                                |
| 346. | <del>Ask your pharmacist how to dispose of medicines no longer required.</del>                        |                                |
| 347. | <del>These measures will help to protect the environment.</del>                                       |                                |
| 348. | • <u>Do not dispose of unused medicine in drains or sewerage systems (e.g.</u>                        |                                |
| 349. | <u>toilets).</u>  |                                |
| 350. | <del>Store at or below 30 °C, in the original pack.</del>   | Moved above.                   |
| 351. | <del>The blisters should be kept in the carton until required for use.</del>                          |                                |
| 352. | <del>Keep out of the reach of children.</del>   |                                |
| 353. |   |                                |
| 354. | <b><u>6. Contents of the pack and other information</u></b>   |                                |
| 355. | <b><u>What [PRODUCT NAME] contains.</u></b>   | Moved from above.              |
| 356. | <del>The active ingredient present in [PRODUCT NAME] tablets substance is</del><br><u>sildenafil.</u> |                                |
| 357. | <del>[PRODUCT NAME] 25: Each film-coated tablet contains sildenafil citrate</del>                     |                                |
| 358. | <u>equivalent to sildenafil 25 mg.</u>  |                                |
| 359. | <del>[PRODUCT NAME] 50: Each film-coated tablet contains sildenafil citrate</del>                     |                                |
| 360. | <u>equivalent to sildenafil 50 mg.</u>  |                                |

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|------|---|---|
| 361. | <del>[PRODUCT NAME] 100: Each film-coated tablet contains sildenafil citrate</del>          |   |
| 362. | <del>equivalent to sildenafil 100 mg.</del>   |   |
| 363. | <del>[PRODUCT NAME] contains the following inactive ingredients: The other</del>            | Aligned to section 6.1 of the annotated amended proposed PI, page 22-23, lines 602-616. |
| 364. | <del>ingredients are Anhydrous calcium hydrogen phosphate, cellulose</del>                  |   |
| 365. | <del>microcrystalline, croscarmellose sodium and magnesium stearate in the</del>            |   |
| 366. | <del>tablet core, and Opadry red (film coating material). The film-coat contains</del>      |   |
| 367. | <del>aluminium lake, hypromellose, indigo carmine, iron oxide red, polyethylene</del>       |   |
| 368. | <del>glycol and titanium dioxide.</del>   |   |
| 369. |   |   |
| 370. | <b>7. PRESENTATION OF [PRODUCT NAME]</b>  | Moved below.  |
| 371. | <del>The [PRODUCT NAME] tablets are packed in PVC/PE/PVdC blister pack</del>                |   |
| 372. | <del>(triplex blister pack), transparent PVC Blister pack and Cold form Blister Pack.</del> |   |
| 373. | <b><del>Transparent PVC Blister Pack:</del></b>   |   |
| 374. | <del>Clear PVC film with hard tempered, heat sealable aluminium foil coated</del>           |   |
| 375. | <del>with heat seal lacquer on inner side foil should be odourless.</del>                   |   |
| 376. | <b><del>PVC/PE/PVdC blister pack (Triplex blister pack):</del></b>                          |   |
| 377. | <del>The pack comprises of clear transparent PVC film, laminated with</del>                 |   |
| 378. | <del>polyethylene (PE) and coated with PVdC on the inner side, with the</del>               |   |
| 379. | <del>backing of hard tempered heat sealable aluminium foil coated with heat</del>           |   |
| 380. | <del>seal lacquer.</del>  |   |
| 381. | <b><del>Cold form blister pack:</del></b>   |   |
| 382. | <del>It comprises of cold forming blister laminate of aluminium foil (one side</del>        |   |
| 383. | <del>bright, soft tempered, plain, dull side lacquered to oriented polyamide film;</del>    |   |
| 384. | <del>bright side lacquer laminated to PVC film) with a backing of hard tempered,</del>      |   |
| 385. | <del>heat sealable aluminium foil coated with heat seal lacquer and of printable</del>      |   |
| 386. | <del>quality.</del>   |   |
| 387. | <del>Carton contains 4 tablets packed in blister. Each blister strip contains 4</del>       |   |
| 388. | <del>tablets.</del>   |   |

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| 389. |   |  |
| 390. | <b>8. IDENTIFICATION OF [PRODUCT NAME]</b>  |  |
| 391. | <b><u>What [PRODUCT NAME] looks like and contents of the pack</u></b>                       |  |
| 392. | [PRODUCT NAME] 25: Red coloured, rounded triangular shaped, film-                           | Aligned to section 3 of the annotated amended proposed PI, page 2, lines 28-36   |
| 393. | coated tablets, with 'S21' engraved on <u>one side</u> and plain on the other <u>side</u> . |  |
| 394. | [PRODUCT NAME] 50: Red coloured, rounded triangular shaped, film-                           |  |
| 395. | coated tablets, with 'S22' engraved on <u>one side</u> and plain on the other <u>side</u> . |  |
| 396. | [PRODUCT NAME] 100: Red coloured, rounded triangular shaped, film-                          |  |
| 397. | coated tablets, with 'S23' engraved on <u>one side</u> and plain on the other <u>side</u> . |  |
| 398. | <u>The [PRODUCT NAME] tablets are packed in PVC/PE/PVdC blister pack</u>                    |  |
| 399. | <u>(triplex blister pack), transparent PVC blister pack and cold form blister</u>           |  |
| 400. | <u>pack.</u>  |  |
| 401. | <b><u>Transparent PVC blister pack:</u></b>   |  |
| 402. | <u>Clear PVC film with hard tempered, heat-sealable aluminium foil coated</u>               | Aligned to section 6.5 of the annotated amended proposed PI, page 23-24, lines 631-651.<br>Aligned to section 6.5 of the annotated amended proposed PI, page 23-24, lines 631-651. |
| 403. | <u>with heat seal lacquer on the inner side of the foil – should be odourless.</u>          |  |
| 404. | <b><u>PVC/PE/PVdC blister pack (triplex blister pack):</u></b>                              |  |
| 405. | <u>The pack comprises of clear transparent PVC film, laminated with</u>                     |  |
| 406. | <u>polyethylene (PE) and coated with PVdC on the inner side, with the a</u>                 |  |
| 407. | <u>backing of hard tempered heat-sealable aluminium foil coated with heat</u>               |  |
| 408. | <u>seal lacquer.</u>  |  |
| 409. | <b><u>Cold form blister pack:</u></b>   |  |
| 410. | <u>It comprises of cold forming blister laminate of aluminium foil (one side</u>            |  |
| 411. | <u>bright, soft tempered, plain, dull side lacquered to oriented polyamide film;</u>        |  |
| 412. | <u>bright side lacquer laminated to PVC film) with a backing of hard tempered,</u>          |  |
| 413. | <u>heat sealable aluminium foil coated with heat seal lacquer and of printable</u>          |  |
| 414. | <u>quality.</u>   |  |
| 415. | <u>Carton contains 4 tablets packed in blister pack. Each blister strip contains</u>        |  |
| 416. | <u>4 tablets.</u>   |  |
| 417. | <u>Not all pack sizes may be marketed.</u>  |  |

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|------|---|--|
| 418. |   |  |
| 419. | <b>9. REGISTRATION NUMBERS</b>                      | Moved below and aligned to PI.   |
| 420. | [PRODUCT NAME] 25: 45/7.1.5/0872                    |  |
| 421. | [PRODUCT NAME] 50: 45/7.1.5/0873                    |  |
| 422. | [PRODUCT NAME] 100: 45/7.1.5/0874                   |  |
| 423. |   |  |
| 424. | <b>10. NAME AND ADDRESS OF REGISTRATION HOLDER</b>  | Applicant details amended as per TOA approval received Amended PI, Section 7, lines 664-675. |
| 425. | <b><u>Holder of Certificate of Registration</u></b> |  |
| 426. | RANBAXY (SA) (PTY) LTD                              |  |
| 427. | a SUN PHARMA company                                |  |
| 428. | Ground Floor, Tugela House                          |  |
| 429. | Riverside Office Park                               |  |
| 430. | 1303 Heuwel Avenue                                  |  |
| 431. | Centurion   |  |
| 432. | (012) 643 2000                                      |  |
| 433. | Ranbaxy Pharmaceuticals (Pty) Ltd.                  |  |
| 434. | a SUN PHARMA company                                |  |
| 435. | 14 Lautre Road                                      |  |
| 436. | Stormill, Ext. 1, Roodepoort                        |  |
| 437. | Johannesburg,                                       |  |
| 438. | 1724.   |  |
| 439. |   |  |
| 440. | <b>11. DATE OF PUBLICATION</b>                      |  |
| 441. | <b><u>This leaflet was last revised in</u></b>      |  |
| 442. | Date of registration: 27 November 2014              |  |
| 443. | Date compliant with Reg 9 and 10: 27 July 2015      |  |
| 444. | <u>To be advised</u>                                |  |
| 445. |   |  |
| 446. | <b><u>9. Registration numbers</u></b>               |  |

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|      |   |   |
|------|---|---|
| 447. | <u>[PRODUCT NAME] 25: To be inserted.</u>   | Moved from above and aligned to Amended PI, Page 25, lines 677-680. |
| 448. | <u>[PRODUCT NAME] 50: To be inserted.</u>   |   |
| 449. | <u>[PRODUCT NAME] 100: To be inserted.</u>  |   |
| 450. |   |   |
| 451. | <u>Namibia:</u>   |   |
| 452. | <u>Raviag 50: <span style="border: 1px solid black; padding: 0 2px;">NS2</span> Reg. no.: 15/7.1/0004</u> |   |
| 453. | <u>Raviag100: <span style="border: 1px solid black; padding: 0 2px;">NS2</span> Reg. no.: 15/7.1/0005</u> |   |