

1.3.2 Proposed Patient Information Leaflet – Clean Copy

This patient information leaflet has been based upon the proposed scientific package insert in Module 1.3.1.

1	SCHEDULING STATUS:	S 3
2	PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:	
3	FRUSEMIDE DEZZO 10 mg/ml	
4	(Injection)	
5	Contains 10,00 mg frusemide per ml.	
6	Read all of this leaflet carefully before you start taking FRUSEMIDE DEZZO 10	
7	mg/ml.	
8	<ul style="list-style-type: none">• Keep this leaflet. You may need to read it again.	
9	<ul style="list-style-type: none">• If you have further questions, please ask your doctor or your pharmacist.	
10	<ul style="list-style-type: none">• FRUSEMIDE DEZZO 10 mg/ml has been prescribed for you personally and	
11	you should not share your medicine with other people. It may harm them,	
12	even if their symptoms are the same as yours.	
13	WHAT FRUSEMIDE DEZZO 10 mg/ml CONTAINS:	
14	The active substance is: frusemide.	
15	The other ingredients are: sodium chloride, water for injections.	

<p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p>WHAT FRUSEMIDE DEZZO 10 mg/ml IS USED FOR:</p> <p>FRUSEMIDE DEZZO 10 mg/ml is classified as a diuretic that works by increasing the amount of salt and water that the kidneys remove from the blood, which causes a decrease in blood volume.</p> <p>FRUSEMIDE DEZZO 10 mg/ml is a medication that is prescribed for the treatment of high blood pressure and fluid retention. This fluid retention may occur due to problems with the heart, kidney, brain or lungs.</p>
<p>23</p> <p>24</p> <p>25</p> <p>26</p> <p>27</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p>	<p>BEFORE YOU ARE GIVEN FRUSEMIDE DEZZO 10 mg/ml:</p> <p>You should not be given FRUSEMIDE DEZZO 10 mg/ml:</p> <ul style="list-style-type: none"> -If you are allergic (hypersensitive) to frusemide or to any other ingredient of FRUSEMIDE DEZZO 10 mg/ml, or to other similar medicines such as sulphonamides (eg. sulfadiazine, cotrimoxazole). -If you are unable to pass urine or if you have kidney failure caused by medication. -If you have a severe condition of the liver called hepatic encephalopathy. - If you have a low blood volume or are dehydrated. - If you are breastfeeding (see “PREGNANCY AND BREASTFEEDING”)
<p>32</p> <p>33</p> <p>34</p> <p>35</p> <p>36</p> <p>37</p> <p>38</p>	<p>Tell your doctor or healthcare professional before being given FRUSEMIDE DEZZO 10 mg/ml if you have or are:</p> <ul style="list-style-type: none"> - Diabetes - Gout - Fluid or electrolyte problems - Difficulty in passing urine - Problems with your prostate

39	- Any hearing difficulties or impairment or experience ringing in the ears or deafness
40	during treatment
41	- Kidney or liver problems
42	- 65 years or older or in premature infants
43	- Low blood pressure or feel dizzy when you stand up
44	- Porphyria as FRUSEMIDE DEZZO 10 mg/ml may cause acute attacks.
45	Receiving FRUSEMIDE DEZZO 10 mg/ml with food and drink:
46	FRUSEMIDE DEZZO 10 mg/ml is an injection. It may be administered with or without a meal.
47	Pregnancy and breastfeeding:
48	If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or
49	other health care professional for advice before FRUSEMIDE DEZZO 10 mg/ml is
50	administered to you.
51	FRUSEMIDE DEZZO 10 mg/ml should not be used if you are pregnant or breastfeeding.
52	Driving and using machinery:
53	FRUSEMIDE DEZZO 10 mg/ml may affect your ability to drive or operate machinery,
54	particularly when you just start using it, or when you change from another medication to
55	this one, or if you consume alcohol while on FRUSEMIDE DEZZO 10 mg/ml treatment.
56	Using other medicines with FRUSEMIDE DEZZO 10 mg/ml:
57	Always tell your healthcare professional if you are taking any other medicine. (This
58	includes complementary or traditional medicines.)

59	Tell your doctor immediately if you are taking digoxin (used for heart problems) or
60	risperidone (used for schizophrenia or bipolar disorders).
61	Also inform your doctor if you are on antibiotics called aminoglycoside antibiotics (eg.
62	kanamycin, gentamycin, tobramycin) or a medicine called cisplatin, as taking these
63	medicines together with FRUSEMIDE DEZZO 10 mg/ml may cause hearing difficulties,
64	such as deafness.
65	If you are taking antibiotics from the cephalosporin class, this may cause kidney
66	problems while on FRUSEMIDE DEZZO 10 mg/ml therapy.
67	There are some medicines that may interact with FRUSEMIDE DEZZO 10 mg/ml. Make
68	sure your doctor knows if you are taking any of the following medicines:
69	-ACE Inhibitors which is used for the treatment of high blood pressure.
70	-Other medicines used for treatment of high blood pressure including other diuretics
71	-Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen etc.
72	The following medicines can affect the way FRUSEMIDE DEZZO 10 mg/ml works
73	and increase the chance of you getting side effects:
74	• Medicines for high blood pressure or heart problems. Your doctor may need to
75	change the dose of your medicine
76	• Medicines for diabetes. These may not work as well when you are using
77	FRUSEMIDE DEZZO 10 mg/ml
78	• Theophylline – used for wheezing or difficulty in breathing

<p>79</p> <p>80</p> <p>81</p> <p>82</p> <p>83</p> <p>84</p> <p>85</p> <p>86</p> <p>87</p> <p>88</p> <p>89</p> <p>90</p>	<ul style="list-style-type: none"> • Phenytoin – used for epilepsy. This can lower the effect of FRUSEMIDE DEZZO 10 mg/ml <p>The following medicines can increase the chance of side effects when taken with FRUSEMIDE DEZZO 10 mg/ml:</p> <ul style="list-style-type: none"> • Lithium – used for mental illnesses. To help stop side effects your doctor may need to change the dose of your lithium and check the amount of lithium in your blood • Cisplatin – used for some cancers • Carbamazepine – used for epilepsy • Methotrexate – used for cancers of the skin, joint or bowel diseases • Corticosteroids – used for inflammation (such as prednisolone) • Probenecid (used to treat gout)
<p>91</p> <p>92</p> <p>93</p> <p>94</p> <p>95</p> <p>96</p> <p>97</p>	<p>HOW TO RECEIVE FRUSEMIDE DEZZO 10 mg/ml:</p> <p>You will not be expected to give yourself FRUSEMIDE DEZZO 10 mg/ml. It will be given by a person who is qualified to do so as a slow injection into your vein or into your muscle.</p> <p>Your doctor will determine your dosage and the duration of your treatment.</p> <p>If you have the impression that the effect of FRUSEMIDE DEZZO 10 mg/ml is too strong or too weak, talk to your doctor or pharmacist.</p>
<p>98</p> <p>99</p>	<p>If you are given more FRUSEMIDE DEZZO 10 mg/ml than you should:</p> <p>As FRUSEMIDE DEZZO 10 mg/ml will be given to you by a doctor or nurse, it is unlikely</p>

<p>100</p> <p>101</p> <p>102</p>	<p>that you will be given too little or too much. However, tell your doctor or nurse if you have any concerns. If you have any further questions about the use of FRUSEMIDE DEZZO 10 mg/ml, ask your doctor or nurse.</p>
<p>103</p> <p>104</p> <p>105</p> <p>106</p> <p>107</p> <p>108</p> <p>109</p> <p>110</p> <p>111</p> <p>112</p> <p>113</p> <p>114</p> <p>115</p> <p>116</p> <p>117</p> <p>118</p> <p>119</p> <p>120</p> <p>121</p> <p>122</p>	<p>POSSIBLE SIDE EFFECTS:</p> <p>FRUSEMIDE DEZZO 10 mg/ml can have side effects.</p> <p>If any of the following happens, stop taking FRUSEMIDE DEZZO 10 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:</p> <ul style="list-style-type: none"> • If you have an allergic reaction. The signs may include inflammation of the kidney (interstitial nephritis), skin rashes, severe blistering of the skin, porphyria (being more sensitive to the sun than usual), high temperature (fever), and itching • Severe stomach or back pain. These could be signs of ‘pancreatitis’ • Bruising more easily, getting more infections, feeling weak or tired more than usual. FRUSEMIDE DEZZO 10 mg/ml can affect the number of blood cells, causing serious blood problems • Increased thirst, headache, feeling dizzy or light-headed, fainting, confusion, muscle or joint pains or weakness, cramps or spasms, or uneven heartbeats. These could be signs of dehydration or changes in your normal body chemicals. Severe dehydration can lead to blood clots. • You notice yellowing of your skin or eyes and your urine becomes darker in colour. These could be signs of a liver problem. • Blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be a condition called Stevens-Johnson

123	syndrome. In a more severe form of the condition called Toxic Epidermal
124	Necrolysis, layers of the skin may peel off to leave large areas of raw exposed
125	skin all over the body.
126	These are all very serious side effects. You may need urgent medical attention or
127	hospitalisation.
128	Tell your doctor immediately or go to the casualty department at your nearest
129	hospital if you notice any of the following:
130	• Problems hearing or ringing in the ears (tinnitus).
131	• Headaches, feeling dizzy or light-headed when standing up quickly.
132	These are all serious side effects. You may need urgent medical attention.
133	Tell your doctor if you notice any of the following:
134	• Low blood potassium levels (hypokalaemia) or other electrolyte imbalances.
135	Symptoms of electrolyte imbalances include: dry mouth, thirst, weakness,
136	lethargy, drowsiness, restlessness.
137	• Feeling sick (nausea) or a general feeling of being unwell, diarrhoea and being
138	sick (vomiting)
139	• Passing more water (urine) than you usually do.
140	If you notice any side effects not mentioned in this leaflet, please inform your doctor or
141	pharmacist.
142	STORING AND DISPOSING OF FRUSEMIDE DEZZO 10 mg/ml:
143	Store at or below 25 °C. Do not refrigerate or freeze. Keep in the outer carton until

144	required for use in order to protect from light.
145	KEEP OUT OF REACH OF CHILDREN.
146	PRESENTATION OF FRUSEMIDE DEZZO 10 mg/ml:
147	2 ml and 5 ml amber coloured, Ph Eur Type I glass ampoules. Cartons of 5 amber
148	glass ampoules.
149	IDENTIFICATION OF FRUSEMIDE DEZZO 10 mg/ml:
150	A clear and colourless to almost colourless solution.
151	REGISTRATION NUMBER
152	47/18.1/0948
153	NAME, ADDRESS AND TELEPHONE NUMBER OF THE REGISTRATION HOLDER
154	Dezzo Trading 392 (Pty) Limited, T/A Indo Pharma
155	Cnr Birch and Bluegum Avenue
156	Anchorville
157	Lenasia
158	1827
159	(011) 857 2090
160	DATE OF PUBLICATION
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