



PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

Columvi 2,5 mg/2,5 mL; Concentrate for solution for infusion

Columvi 10 mg/10 mL; Concentrate for solution for infusion

The active substance is glofitamab

Contains sugar (sucrose) 205,4 mg for 2,5 mg/2,5 mL vial,

and 821,5 mg for 10 mg/10 mL vial

Read all of this leaflet carefully before you are given Columvi

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse or other health care provider.

What is in this leaflet

1. What Columvi is and what it is used for
2. What you need to know before you take Columvi
3. How to use Columvi
4. Possible side effects
5. How to store Columvi
6. Contents of the pack and other information



22 **1. What Columvi is and what it is used for**

23 **What Columvi is**

24 Columvi is a cancer medicine that contains the active substance glofitamab.

25

26 **What Columvi is used for**

27 Columvi is used to treat adults with a cancer called “diffuse large B-cell lymphoma” (DLBCL).

28 Columvi can be given alone (monotherapy) or with chemotherapy medicines.

- 29 • Columvi is used alone when the cancer has come back (relapsed) or did not respond to
- 30 previous treatments (refractory) and when you have received two or more prior treatments.
- 31 • Columvi is used with the medicines gemcitabine and oxaliplatin when the cancer has come
- 32 back (relapsed) or did not respond to previous treatments (refractory) and when you cannot
- 33 receive a stem cell transplant.

34 Diffuse large B-cell lymphoma is a cancer of a part of your immune system (the body’s defences).

- 35 • It affects a type of white blood cell called ‘B-cells’.
- 36 • In DLBCL, B cells multiply in an uncontrolled manner and build up in your tissues.

37

38 **How Columvi works**

39 Columvi binds to the surface of these cancerous B cells and also to the surface of T cells (another

40 type of white blood cell). This binding on two targets activates T cells which causes them to

41 multiply and causes the rapid breakdown of the cancerous B cells.

42

43 **2. What you need to know before you are given Columvi**



Columvi should not be administered to you:

- if you are allergic (hypersensitive) to glofitamab or any of the other ingredients of Columvi (see Section 6 for a complete list of ingredients in Columvi).

If you are not sure, talk to your doctor or nurse before you are given Columvi.

Warnings and precautions

Tell your doctor or health care provider before being given Columvi if:

- you have an infection
- you have had a long-lasting infection (chronic) or an infection which keeps coming back (recurring)
- you have or had any kidney, liver, or heart problems

Special care should be taken with Columvi: Pay attention to the following serious side effects.

These can sometimes be life-threatening and may happen any time during Columvi treatment.

Tell your doctor immediately if you experience any of the following side effects while receiving Columvi:

- if you experience fever, fast heartbeat, feeling dizzy or lightheaded, chills, or shortness of breath. These may be symptoms of a condition known as cytokine release syndrome, a serious condition.
- if you experience confusion, disorientation, sleepiness, or change in consciousness level. These symptoms could be a sign of a problem with your nervous system caused by your immune cells. This is known as neurologic toxicity including immune effector cell-associated neurotoxicity syndrome.



- 67 • if you develop fever, chills, difficulty breathing, or burning sensation while passing urine.
68 These may be signs of an infection. Some infections may be life-threatening or fatal.
69 • if you experience kidney problems (weakness, shortness of breath, fatigue, and confusion),
70 heart problems (fluttering of the heart or a faster or slower heartbeat), vomiting or
71 diarrhoea, and tingling in the mouth, hands, or feet. These may be signs of a condition
72 called tumour lysis syndrome.
73 • your cancer appears to become worse and you develop tender swollen lymph nodes, chest
74 pain, cough, inability to breathe easily, or pain at the site of the tumour. These may be
75 symptoms of tumour flare.

76 If you have any of the above symptoms tell your doctor straight away.

77 Your doctor may:

- 78 • give you other medicines to reduce symptoms and prevent complications
79 • stop your treatment for a short time, or
80 • stop your treatment completely

81

82 **Children and adolescents (< 18 years)**

83 Columvi should not be used in children or adolescents under 18 years of age. This is because
84 Columvi has not been studied in this age group.

85

86 **Other medicines and Columvi**

87 Tell your doctor or nurse if you are taking, have recently taken, or might start taking any other
88 medicines. This includes medicines obtained without a prescription and herbal medicines.

89

90 **Pregnancy and breastfeeding**

DS
BH



91 *Pregnancy and contraception*

- 92 • Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become
93 pregnant.
- 94 • You should not be given Columvi if you are pregnant. This is because it is possible that
95 Columvi could harm your unborn baby.
- 96 • If you could become pregnant, you must use effective contraception while you are being
97 treated with Columvi and for 2 months after the last dose.
- 98 • If you become pregnant while you are being treated with Columvi tell your doctor
99 immediately.

100 *Breastfeeding*

101 Do not breast-feed while receiving Columvi and for at least 2 months after the last dose. This is
102 because it is not known if this medicine can pass into breast milk and harm your baby.

103

104 **Driving and using machines** Columvi is not likely to affect your ability to drive, cycle, or use any
105 tools or machines.

106 However, if you experience symptoms of cytokine release syndrome (such as fever, fast heartbeat,
107 feeling dizzy or lightheaded, chills or shortness of breath) or neurologic toxicity including immune
108 effector cell-associated neurotoxicity syndrome – do not drive, cycle, or use any tools or machines
109 until you feel better.

110

111 **3. How to use Columvi**

112 You will be given Columvi under the supervision of a doctor experienced in cancer treatment, in a
113 hospital or clinic.

114 ***Medicines given before Columvi treatment***

DS
Bh



- 115 • Seven days before starting Columvi treatment, you will be given another medicine,
116 obinutuzumab, to deplete the B cells in your blood in order to prevent cytokine release
117 syndrome.
- 118 • During the 30 to 60 minutes before you are given Columvi, you may be given other
119 medicines (pre-medication) to help reduce reactions associated with cytokine release
120 syndrome. These medicines may include:
- 121 – A corticosteroid such as dexamethasone
- 122 – A fever-reducing medicine such as paracetamol
- 123 – An antihistamine such as diphenhydramine
- 124

125 ***How much and how often you will receive Columvi***

126 You will be given 12 treatment cycles of Columvi.

- 127 • Each cycle lasts 21 days.

128 Your doctor will begin Columvi treatment with a low-dose and will gradually increase it to the full
129 dose.

130

131 A typical schedule is shown below.

132 Cycle 1: This will include a pre-treatment and 2 low doses of Columvi during the 21 days:

- 133 • Day 1 – Pre-treatment with obinutuzumab
- 134 • Day 8 – 2,5 mg starting dose of Columvi dose
- 135 • Day 15 – 10 mg intermediate dose of Columvi
- 136 Cycle 2 to Cycle 12: This will be just one dose in the 21 days:



- 137 • Day 1 – 30 mg full dose of Columvi

138

139 ***How Columvi is given and monitoring***

140 Columvi is given as a drip into a vein (an intravenous infusion). Your doctor will adjust the time
141 required for infusion depending on how you respond to treatment.

- 142 • Your first infusion will be given over 4 hours.
- 143 • When Columvi is given alone, your doctor will monitor you carefully during the first infusion
144 and for 10 hours after completion of infusion.
- 145 • When Columvi is given with the medicines gemcitabine and oxaliplatin, your doctor will
146 monitor you carefully during and after completion of the first infusion for a combined total of
147 8 hours.
- 148 • This is to watch for any signs or symptoms of cytokine release syndrome.
- 149 • For following infusions, your doctor may require to monitor you after completion of infusion.
150 This will be necessary if you have had moderate or severe CRS with your previous dose.
- 151 • If you do not have any cytokine release syndrome after 3 doses, your doctor may give the
152 following infusions over 2 hours.

153

154 **If you miss a dose of Columvi**

155 If you miss an appointment, make another one straight away. For the treatment to be fully
156 effective, it is very important not to miss a dose.

157

158 **If you stop using Columvi**

159 Speak with your doctor before stopping treatment. This is because stopping treatment may make
160 your condition worse.



161 Ask your doctor if you have any further questions on the use of this medicine.

162

163 **4. Possible side effects**

164 Columvi can cause side effects

165 Not all side effects reported for Columvi are included in this leaflet. Should your general health
166 worsen or if you experience any untoward effects while taking Columvi, please consult your health
167 care provider for advice.

168 The following side effects have been reported with this medicine:

169 **Serious side effects**

170 **Tell your doctor immediately if you get any of the serious side effects listed below** – you may
171 need urgent medical treatment.

- 172 • Cytokine release syndrome; symptoms include fever, fast heartbeat, feeling dizzy or
173 lightheaded, chills, and shortness of breath
- 174 • Neurologic toxicity including immune effector cell-associated neurotoxicity syndrome;
175 symptoms include confusion, disorientation, sleepiness, and change in consciousness level
- 176 • Infection; symptoms include fever, chills, difficulty breathing, and burning pain when
177 passing urine
- 178 • Tumour flare; symptoms include tender swollen lymph nodes, chest pain, inability to
179 breathe easily, and pain at the site of the tumour
- 180 • Tumour lysis syndrome; symptoms include weakness, shortness of breath, feeling
181 confused, irregular heartbeat, and muscle cramps

182 **Other side effects**

183 ***Columvi monotherapy***

184 Tell your doctor or nurse if you notice any of the following side effects or if they get worse:

DS
BH

185 **Very common (may affect more than 1 in 10 people)**

- 186 • Reduced levels in blood tests of:
- 187 – neutrophils (a type of white blood cell), which may cause fever or any symptoms
- 188 of an infection
- 189 – red blood cells (anaemia), which may cause tiredness, feeling unwell, and pale
- 190 skin
- 191 – platelets (a type of blood cell), which may cause unusual bruising or bleeding
- 192 • fever
- 193 • Low levels in blood tests of:
- 194 – phosphate, magnesium, calcium, or potassium
- 195 • rash
- 196 • constipation
- 197 • diarrhoea
- 198 • feeling sick (nausea)
- 199 • headache
- 200 •

201 **Common (may affect up to 1 in 10 people)**

- 202 • low sodium levels in blood tests, which may cause tiredness, muscle twitching, or cramps
- 203 • increased levels in blood tests of liver enzymes and bilirubin (yellow substance in blood)
- 204 which may cause yellowing of skin or eyes and dark urine
- 205 • bacterial infections, such as urinary tract infection and infection in or around the stomach
- 206 • respiratory tract infections, such as runny nose, sore throat, sinus infections, and chest
- 207 colds
- 208 • reduced levels in blood tests of lymphocytes (a type of white blood cell), that may affect the
- 209 body's ability to fight infection
- 210 • infection in blood (sepsis), which may cause fever, chills, and confusion



- 211 • fungal infection
- 212 • fever with low levels of neutrophils (a type of white blood cell)
- 213 • lung infection (pneumonia) which may cause fever, cough, and difficulty breathing
- 214 • vomiting
- 215 • bleeding in the stomach or gut (gastrointestinal haemorrhage), which may cause black
- 216 stools or blood in vomit
- 217 • confusion
- 218 • trembling
- 219 • sleepiness

220 **Uncommon (may affect less than 1 in 100 people)**

- 221 • swelling of the spinal cord (myelitis), which may cause muscle weakness or numbness
- 222 • inflammation of the large bowel, which may cause abdominal pain, bloody stools and urge
- 223 to have a bowel movement

224

225 ***Columvi in combination with gemcitabine and oxaliplatin***

226 Tell your doctor or nurse if you notice any of the following side effects or if they get worse:

227 **Very common (may affect more than 1 in 10 people)**

- 228 • reduced levels in blood tests of:
 - 229 – platelets (a type of blood cell), which may cause unusual bruising or bleeding
 - 230 – neutrophils (a type of white blood cell), which may cause fever or any symptoms of an
 - 231 infection
 - 232 – red blood cells (anaemia), which may cause tiredness, feeling unwell, and pale skin
 - 233 – lymphocytes (a type of white blood cell), that may affect the body's ability to fight infection
- 234 • feeling sick (nausea)



- 235 • numbness, tingling, a burning sensation, pain, discomfort or weakness and/or difficulty walking
236 (peripheral neuropathy)
- 237 • diarrhoea
- 238 • increased levels in blood tests of liver enzymes
- 239 • rash
- 240 • fever
- 241 • vomiting
- 242 • pain in the muscles and bones
- 243 • abdominal (belly) pain
- 244 • constipation
- 245 • low levels in blood tests of potassium (hypokalaemia) or sodium (hyponatremia)
- 246 • COVID-19 infection caused by a virus called coronavirus (SARS-CoV-2)
- 247 • respiratory tract infections, such as runny nose, sore throat, sinus infections, and chest colds
- 248 • lung infection (pneumonia) which may cause fever, cough, and difficulty breathing
- 249
- 250 **Common (may affect up to 1 in 10 people)**
- 251 • headache
- 252 • low levels in blood tests of magnesium, calcium, or phosphate
- 253 • new or recurring viral infections, such as shingles and cytomegalovirus infection
- 254 • bacterial infections, such as urinary tract infection
- 255 • infection in blood (sepsis), which may cause fever, chills, and confusion
- 256 • fungal infection
- 257 • increased level of bilirubin in the blood which may cause yellowing of skin or eyes

DS
Blt



- 258 • fever with low levels of neutrophils (a type of white blood cell)
- 259 • inflammation of the large bowel, which may cause abdominal pain, bloody stools and urge to
- 260 have a bowel movement
- 261 • inflammation of the pancreas
- 262 • inflammation of the lungs (pneumonitis), which may cause cough and difficulty breathing

263

264

265 **Uncommon (may affect less than 1 in 100 people)**

- 266 • trembling
- 267 • elevated liver enzymes (shown in tests), which may be a sign of an inflamed liver
- 268 • lung infection (pneumocystis jirovecii pneumonia)

269

270 **Reporting of side effects**

271 If you get side effects, talk to your doctor, or pharmacist or nurse. You can also report side effects
272 to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-
273 umc.org) found on SAHPRA website. By reporting side effects, you can help provide more
274 information on the safety of Columvi.

275

276 **5. How to store Columvi**

277 Columvi will be stored by your doctor at the hospital or clinic. The storage details are as follows:

- 278 • Keep this medicine out of the sight and reach of children.
- 279 • Do not use this medicine after the expiry date which is stated on the carton and label after
- 280 EXP. The expiry date refers to the last day of that month.
- 281 • Store in a refrigerator (2 °C to 8 °C).



- 282 • Do not freeze.
- 283 • Keep the vial in the outer carton in order to protect from light.
- 284 • Do not use this medicine if it appears cloudy, discoloured, or contains particles.
- 285 Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how
- 286 to throw away any medicines you no longer use. These measures will help protect the
- 287 environment.
- 288 Columvi is for single use only. Any unused product or waste material should be disposed of in
- 289 accordance with local requirements.

290

291 **6. Contents of the pack and other information**

292 What Columvi contains

- 293 • The active substance is glofitamab.
- 294 • Columvi 2,5 mg/2,5 mL: Each vial contains 2,5 milligrams of glofitamab (in 2,5 mL).
- 295 • Columvi 10 mg/10 mL: Each vial contains 10 milligrams of glofitamab (in 10 mL).
- 296 • The other ingredients are:
- 297 - L-Histidine,
- 298 - L-Histidine Hydrochloride monohydrate,
- 299 - L-Methionine,
- 300 - Polysorbate 20,
- 301 - D-Sucrose,
- 302 - Water for Injection

303

304 **What Columvi looks like**



305 Columvi 2,5 mg/vial: Pack of 1 vial. Colourless 6 mL, Type I, borosilicate glass vial with a
306 flouoresin laminated grey rubber stopper, sealed with an aluminium seal with pink plastic flip-off
307 cap.

308 Columvi 10 mg/vial: Pack of 1 vial. Colourless 15 mL, Type I, borosilicate glass vial with a
309 flouoresin laminated grey rubber stopper, sealed with an aluminium seal with avocado plastic flip-
310 off cap.

311

312 **Holder of Certificate of Registration**

313 Roche Products (Pty) Ltd

314 90 Bekker Road

315 Hertford Office Park

316 Building E, Vorna Valley

317 Midrand

318 Gauteng

319 South Africa

320 Roche Ethical Assistance Line toll-free: 0800 21 21 25

321

322 **This leaflet was last revised in**

323 10 May 2026

324

325 **Registration number**

326 Columvi 2,5 mg/2,5 mL: 57/30.5/0287

DS
BH



327 Columvi 10 mg/10 mL: 57/30.5/0288

328