1		**Reference**
2	**SCHEDULING STATUS** **S3**	
3	**MARACOXA 60** (film-coated tablet)	
4	**MARACOXA 90** (film-coated tablet)	
5	**MARACOXA 120** (film-coated tablet)	
6	Etoricoxib 60 mg/90 mg/120 mg respectively per tablet	
7 8	Contains sugar: Lactose monohydrate 1,680 mg, 2 520 mg and 3,360 mg respectively	
9 10	This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium free'.	
11		
12 13 14 15 16 17 18	**Read all of this leaflet carefully before you start taking MARACOXA** • Keep this leaflet. You may need to read it again. • If you have further questions, please ask your doctor, ~~or~~ pharmacist, nurse or other healthcare provider. • MARACOXA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.	PIL guideline
19		
20	**What is in this leaflet**	
21	1. What MARACOXA is and what it is used for.	
22	2. What you need to know before you take MARACOXA.	
23	3. How to take MARACOXA.	
24	4. Possible side effects.	
25	5. How to store MARACOXA.	

26	6. Contents of the pack and other information.	
27		
28 29 30 31 32 33	**1. What MARACOXA is and what it is used for** • The active ingredient etoricoxib belongs to a group of medicines called COX-2 inhibitors. These belong to a family of medicines called non-steroidal anti-inflammatory medicines. • Your doctor has prescribed MARACOXA for one of the following conditions:	
34	- relief of symptoms of osteoarthritis,	
35	- relief of symptoms of rheumatoid arthritis,	
36	- treatment of ankylosing spondylitis,	
37 38	- short term relief of acute pain, treatment limited to a maximum period of 8 days,	
39	- treatment of moderate to severe acute pain after dental surgery,	
40	- treatment of menstrual pain,	
41	- treatment of acute gout attacks.	
42		
43	**2. What you need to know before you take MARACOXA**	
44	**Do not take MARACOXA:**	
45 46	• If you are hypersensitive (allergic) to ~~the active substance~~ etoricoxib or any of the other ingredients of MARACOXA <u>(listed in section 6).</u>	PIL guideline
47 48	• If you are allergic to non-steroidal anti-inflammatory medicines, including aspirin and COX-2 inhibitors, such as MARACOXA.	
49	• If you have a stomach ulcer or bleeding in your stomach or intestines.	
50	• If you have a serious liver disease.	
51	• If you have a serious kidney disease.	

52 53	• If you are pregnant or breastfeeding *(see 'Pregnancy and breastfeeding and fertility')*.	
54 55	• Do not give to children or adolescents under 16 years of age as safety and efficacy have not been established.	
56	• If you have an inflammatory bowel disease.	
57 58 59 60 61 62 63 64	• If your doctor has diagnosed heart problems including heart failure (moderate or severe), angina (chest pain) or if you have had a heart attack, bypass surgery, peripheral arterial disease (poor circulation in legs or feet due to narrow or blocked arteries), or any kind of stroke (including mini-stroke, transient ischaemic attack or TIA). Etoricoxib may slightly increase your risk of heart attack and stroke, and this is why it should not be used in those who have already had heart problems or stroke.	
65 66 67	• If you have high blood pressure that has not been controlled by treatment (check with your doctor or nurse if you are not sure whether your blood pressure is adequately controlled).	
68	• If you are having heart bypass.	
69 70	• If you are taking lithium (a medicine used to treat some types of depression).	
71 72	• If you are taking digoxin (a medicine for heart failure and irregular heart rhythm).	
73		
74	**Warnings and precautions**	
75	**Take special care with MARACOXA:**	
76 77 78	**MARACOXA may cause serious health conditions such as involving the heart, gastrointestinal (stomach) or skin reactions which may be fatal.**	

79	• If you have a history of stomach bleeding or ulcers.	
80 81	• If you are dehydrated due to loss of too much water from the body, for example by being sick, diarrhoea or sweating.	
82	• If you have swelling due to fluid retention.	
83 84	• If you have a history of heart failure or any other form of heart disease.	
85 86 87 88	• If you have a history of high blood pressure. MARACOXA can increase blood pressure in some people, especially in high doses, and your doctor will want to check your blood pressure from time to time.	
89	• If you have any history of liver or kidney disease.	
90 91	• If you are being treated for an infection, MARACOXA can mask or hide a fever, which is a sign of infection.	
92	• If you are a woman trying to become pregnant.	
93	• If you are elderly (i.e. over 65 years of age).	
94 95	• If you have diabetes, high cholesterol or are a smoker. These can increase your risk of heart disease.	
96 97	If you are not sure if any of the above apply to you, talk to your doctor before taking MARACOXA to find out if this medicine is suitable for you.	
98		
99 100	**Codeine/NSAIDs (as contained in MARCOXA) combinations contains codeine, which is an opioid medicine.**	
101 102 103 104 105	Repeated use of codeine/NSAIDs (as contained in MARCOXA) combinations may result in you becoming accustomed to it (needing to take higher doses). Repeated use of codeine/NSAIDs (as contained in MARCOXA) combinations may also lead to dependence, abuse and	

106 107	addiction, which may result in life-threatening overdose due to the codeine component.	
108 109 110 111 112 113 114	~~If you are taking codeine/NSAIDs (as contained in MARCOXA) combinations for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (*see section 4).*~~	1.0_Attach 1: PVC letter dated 08/03/2024 – removal of safety signals (risk of RTA & hypokalaemia associated with the use of NSAIDs). Module 1.5.5.1, proposed PI, section 4.4, pg 7
115 116 117	If you experience any of the following signs whilst taking codeine/NSAIDs (as contained in MARCOXA) combinations, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.	
118	• You need to take this medicine for longer than advised.	
119	• You need to take more than the recommended dose.	
120 121	• You are using this medicine for reasons other than medical reasons, for instance, ‘to stay calm’ or to ‘help you sleep’.	
122 123	• You have made repeated, unsuccessful attempts to quit or control the use of this medicine.	
124 125	• When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again (‘withdrawal effects’).	
126		
127	**Other medicines and MARACOXA:**	
128 129	Always tell your healthcare ~~professional~~ <u>provider</u> if you are taking any other medicine. (This includes complementary or traditional medicines).	PIL guideline
130	• Medicines that thin your blood (anticoagulants), such as warfarin.	
131	• Rifampicin (an antibiotic).	

132 133	• Methotrexate (a medicine used for suppressing the immune system and often used in rheumatoid arthritis).	
134 135	• Medicines used to help control high blood pressure and heart failure called ACE inhibitors and angiotensin receptor blockers.	
136 137	• Lithium (a medicine used to treat some types of depression) *(see 'Do not take MARACOXA').*	
138	• Diuretics (water tablets).	
139 140	• Ciclosporin and tacrolimus (medicines used for suppressing the immune system).	
141 142	• Digoxin (a medicine for heart failure and irregular heart rhythm) *(see 'Do not take MARACOXA').*	
143	• Minoxidil (a medicine used to treat high blood pressure).	
144	• Salbutamol tablets or oral solution (a medicine for asthma).	
145	• Birth control pills.	
146	• Hormone replacement therapy.	
147 148	• Aspirin, the risk of stomach ulcers is greater if you take MARACOXA with aspirin.	
149 150	• Do not take high dose aspirin or other anti-inflammatory medicines while you are taking MARACOXA.	
151 152 153	• If you are taking low dose aspirin to prevent heart attacks or stroke, you should not stop taking aspirin until you talk to your doctor.	
	• If you are taking medicines called furosemide and thiazides.	
154		
155 156	Remember to tell your doctor if you start taking any other medicines while you are receiving MARACOXA**.**	
157		
158	**MARACOXA with food and drink and alcohol:**	

159	MARACOXA can be taken with or without food.	
160		
161	**Pregnancy and breastfeeding and fertility**	
162 163 164	MARACOXA should not be taken during pregnancy. If you think you could be pregnant, or if you are planning to become pregnant, stop taking the tablets and consult your doctor.	
165		
166 167	It is not known if MARACOXA is excreted in human milk. If you are using MARACOXA, you must not breastfeed.	
168		
169 170 171 172 173 174	~~If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MARACOXA.~~ If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.	Reworded as per PIL guideline
175		
176	**Driving and using machines~~ry~~:**	PIL guideline
177 178 179 180	It is not always possible to predict to what extent MARACOXA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MARACOXA affects them.	
181 182	• Dizziness and sleepiness have been reported in some patients taking etoricoxib, as in MARACOXA**.**	
183	• Do not drive if you experience dizziness or sleepiness.	
184 185	• Do not use any tools or machines if you experience dizziness or sleepiness.	

186	**Important information about some of the ingredients of MARACOXA:**	
187 188 189 190 191 192 193	• MARACOXA contains lactose, a type of sugar, which may have an effect on the control of your blood sugar if you have diabetes mellitus. ~~If you have been told by your doctor that you cannot tolerate or digest some sugars (have intolerance to some sugars) talk to your doctor before taking MARACOXA tablets.~~ • If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.	Reworded as per EC guideline on excipients
194 195	• This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium free'.	
196		
197	**3. How to take MARACOXA:**	
198	Do not share medicines prescribed for you with any other person.	
199 200 201 202	~~Always take MARACOXA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.~~ Always take MARACOXA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.	Reworded as per PIL guideline
203	• Do not take more than the recommended dose for your condition.	
204	• Your doctor will want to discuss your treatment from time to time.	
205 206 207 208	• It is important that you use the lowest dose that controls your pain, and you should not take MARACOXA for longer than necessary. This is because the risk of heart attacks and strokes might increase after prolonged treatment, especially with high doses.	
209 210	• MARACOXA tablets should not be taken by children or adolescents under 16 years of age.	
211	• Take MARACOXA tablets once a daily by mouth.	
212	• MARACOXA can be taken with or without food.	

213 214	• Your doctor will decide what dose of MARACOXA you should take and how long you should take it.	
215 216	• If you have the impression that the effect of MARACOXA is too strong or too weak, tell your doctor or pharmacist.	
217		
218	The usual dose is:	
219	**For relief of symptoms of osteoarthritis:**	
220	- The recommended dose is 60 mg once daily.	
221	**For relief of symptoms for rheumatoid arthritis:**	
222	- The recommended dose is 90 mg once a day.	
223	**For the treatment of ankylosing spondylitis:**	
224	- The recommended dose is 90 mg once a day.	
225	**Acute pain conditions:**	
226 227	- The recommended dose is 90 or 120 mg once daily, limited to a maximum of 8 days treatment.	
228	**For the relief of gout attacks:**	
229 230	- The recommended dose is 120 mg once a day which should only be used for the acute painful period, limited to a maximum of 8 days treatment.	
231	**For the treatment of menstrual pain:**	
232 233	- The recommended dose is 120 mg once a day which should only be used for the acute painful period.	
234	**For relief of pain after dental surgery:**	
235	- The recommended dose is 90 mg once daily.	
236		
237	**If you take more MARACOXA than you should:**	
238 239	In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison ~~control~~ centre.	PIL guideline

240	**If you forget to take MARACOXA:**	
241	Do not take a double dose to make up for forgotten individual doses.	
242		
243	**4. Possible side effects:**	
244	MARACOXA can have side effects:	
245 246 247 248	Not all side effects reported for MARACOXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MARACOXA, please consult your ~~doctor, pharmacist or~~ healthcare ~~professional~~ provider for advice.	PIL guideline
249		
250 251 252	**If any of the following happens, stop taking MARACOXA and call your doctor immediately or go to the casualty department at your nearest hospital:**	
253 254 255	• An allergic reaction - which can include skin problems such as ulcers or blistering, swelling of the face, lips, tongue or throat, which may cause difficulty in swallowing or breathing.	
256 257	• Shortness of breath, chest pains, or ankle swelling appear or if they get worse.	
258 259 260 261 262 263 264 265	• ~~Codeine/NSAIDs (as contained in MARCOXA) combinations, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (*see section 2*). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.~~	1.0_Attach 1: PVC letter dated 08/03/2024 – removal of safety signals (risk of RTA & hypokalaemia associated with the use of NSAIDs). Module 1.5.5.1, proposed PI, section 4.8, pgs 18 & 21

266 267 268	These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MARACOXA**.** You may need urgent medical attention or hospitalisation.	
269		
270 271	**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**	
272 273	• Yellowing of the skin and eyes (jaundice) – these are signs of liver disorders.	
274	• Severe or continual stomach pain or your stools become black.	
275	These are all serious side effects. You may need urgent medical attention.	
276		
277	**Tell your doctor if you notice any of the following:**	
278	*The following side effects have been reported frequently:*	
279	• Stomach pain;	
280	• swelling of the legs and/or feet due to fluid retention (oedema);	
281	• dizziness, headache;	
282	• palpitations (fast or irregular heartbeat);	
283 284 285 286 287 288	• irregular heart rhythm (arrhythmia);	Module 1.5.5.1, proposed PI, section 4.8, Cardiac disorders, pg 19. Moved from below (Less frequent). Dysrhythmia reworded to arrhythmia.
289	• wheezing or shortness of breath (bronchospasms);	
290	• wind (excessive gas), gastritis (inflammation of the lining of the stomach), heartburn, diarrhoea, indigestion (dyspepsia)/stomach	

291 292	discomfort, nausea, being sick (vomiting), inflammation of the oesophagus, mouth ulcers;	
293	• weakness and fatigue, flu-like illness.	
294		
295	*The following side effects have been reported less frequently:*	
296 297 298	• Gastroenteritis (inflammation of the gastrointestinal tract that involves both the stomach and small intestine/stomach flu), upper respiratory infection, urinary tract infection;	
299 300	• decreased number of red blood cells, decreased number of white blood cells, platelets decreased;	
301 302	• hypersensitivity (an allergic reaction including hives which may be serious enough to require immediate medical attention);	
303 304 305	• ~~irregular heart rhythm (dysrhythmia);~~	Dysrhythmia reworded to arrhythmia and moved to "Frequent" above.
306	• constipation, appetite increases or decreases, weight gain;	
307 308	• anxiety, depression, decreases in mental sharpness; confusion; seeing, feeling or hearing things that are not there (hallucinations);	
309	• taste alteration, inability to sleep, numbness or tingling, sleepiness;	
310	• blurred vision, eye irritation and redness;	
311 312	• ringing in the ears, vertigo (sensation of spinning while remaining still);	
313 314 315	• abnormal heart rhythm (atrial fibrillation), fast heart rate, heart failure, feeling of tightness, pressure or heaviness in the chest (angina pectoris), heart attack;	
316 317	• flushing, stroke, mini-stroke (transient ischaemic attack), severe increase in blood pressure;	

318	• cough, breathlessness, nosebleed;	
319 320 321 322	• stomach or bowel bloating, vomiting, changes in your bowel habits, dry mouth, stomach ulcer, inflammation of the stomach lining that can become serious and may lead to bleeding, irritable bowel syndrome, inflammation of the pancreas;	
323	• swelling of the face, skin rash or itchy skin, redness of the skin;	
324	• muscle cramp/spasm, muscle pain/stiffness;	
325 326	• high levels of potassium in your blood, changes in blood or urine tests relating to your kidney, serious kidney disorders;	
327	• chest pain;	
328 329 330 331 332 333	• angioedema (an allergic reaction with swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing, which may be serious enough to require immediate medical attention) /anaphylactic /anaphylactoid reactions including shock (a serious allergic reaction that requires immediate medical attention);	
334	• confusion, restlessness;	
335	• liver problems (hepatitis);	
336	• low blood levels of sodium;	
337	• liver failure, yellowing of the skin and/or eyes (jaundice);	
338	• severe skin reactions.	
339		
340 341 342 343	~~*The following side effects have been reported but the frequency is unknown:*~~	Module 1.5.5.1, section 4.8, Pg 17 -21, 'Frequency unknown' updated in the PI.
	~~• Increased blood pressure;~~	Moved to frequent. Module

344 345		1.5.5.1, section 4.8, Pg 19 (Vascular disorders)
346 347 348 349	~~• irregular heart rhythm (dysrhythmia).~~	This S/E is already above under “less frequent” section. Updated and moved to ’Frequent’
350 351	If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.	
352		
353	**Reporting of side effects**	
354 355 356 357 358 359 360 361 362 363 364 365	~~If you get side effects, talk to your doctor, pharmacist or healthcare professional. Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions~~ If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “~~**6.04 Adverse Drug Reactions Reporting Form**~~”, ~~found online under SAHPRA’s publications:~~ ~~https://www.sahpra.org.za/Publications/Index/8~~ Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **MARACOXA**.	Reworded as per PIL guideline and updated as per Module 1.5.5.1, section 4.8, ‘Reporting of suspected adverse reactions’, pg 22
366		
367	**5. How to store MARACOXA**	
368	Store at or below 30 °C.	
369 370	Blisters: Store in the original package in order to protect from moisture and keep in the carton until required for use.	

371		
372	Bottles: Keep the container tightly closed in order to protect from moisture.	
373	Do not use after the expiry date stated on the label.	
374	Return all unused medicine to your pharmacist.	
375 376	Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).	
377	Do not store in a bathroom.	
378	Store all medicines out of reach of children.	
379		
380	**6. Contents of the pack and other information**	
381	**What MARACOXA contains:**	
382	The active substance is etoricoxib.	
383	The other ingredients are:	
384	**MARACOXA 60:**	
385 386 387 388 389 390	Core: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, silica colloidal anhydrous, {coating: Opadry II green 31K510020 (composition: HPMC hypromellose (15cP), lactose monohydrate, titanium dioxide, triacetin, iron oxide yellow, FD&C blue #2/indigo carmine aluminium lake (dye strength (11 % - 14 %), carnuba wax)}.	
391		
392	**MARACOXA 90:**	
393 394 395 396 397	Core: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, silica colloidal anhydrous, Coating: Opadry II white 31K580000 (composition: HPMC hypromellose (15cP), lactose monohydrate, titanium dioxide, triacetin, carnuba wax)}.	

398		
399	**MARACOXA 120:**	
400 401 402 403 404 405	Core: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium (Ac-Di-Sol), magnesium stearate, silica colloidal anhydrous, Coating: Opadry II green 31K510019 (composition: HPMC hypromellose (15cP), lactose monohydrate, titanium dioxide, triacetin, FD&C blue #2/indigo carmine, aluminium lake (dye strength (3 %-5 %), iron oxide yellow, carnuba wax)}	
406		
407	**What MARACOXA looks like and contents of the pack:**	
408	**What MARACOXA looks like:**	
409	**MARACOXA 60:**	
410 411	A green film-coated, round, biconvex, bevelled edge tablet debossed with “E” on one side and “60” on the other side.	
412		
413	**MARACOXA 90:**	
414 415	A white film-coated, round, biconvex, bevelled edge tablet debossed with “E” on one side and “90” on the other side.	
416		
417	**MARACOXA 120:**	
418 419	A pale green film-coated, round, biconvex, bevelled edge tablet debossed with “E” on one side and “120” on the other side.	
420		
421	**Contents of the pack:**	
422 423 424	Cold form blister pack comprises of cold form laminate (aluminium foil laminated to oriented polyamide on one side and laminated to PVC on other	

425	side i.e. OPA/Al/PVC) on one side and hard tempered aluminum foil (coated with VMCH heat seal lacquer) on the other side.	
426 427 428	Suitable number of blister strips will be placed in an outer cardboard carton. The number of tablets per strip and the number of strips in carton shall be based on commercial requirement.	
429		
430 431 432 433	PVC/PVdC blister pack comprises of clear, transparent PVC laminated with PVdC on one side and hard tempered aluminium foil coated with heat seal lacquer on other side (PVdC/PVC/Al). Heat seal lacquer contains 86 % Vinyl Chloride, 13 % Vinyl Acetate & 1 % maleic acid.	
434 435 436	Suitable number of blister strips will be placed in an outer cardboard carton. The number of tablets per strip and the number of strips in each carton shall be based on commercial requirement.	
437		
438 439 440	HDPE bottle pack comprises of round wide mouth white high-density polyethylene (HDPE) bottle with white opaque polypropylene (PP) screw closure with induction sealing liner along with wad.	
441 442	The HDPE bottle pack may either be placed in an outer cardboard carton or provided without a carton based on commercial requirement.	
443		
444	Pack sizes:	
445	**60 mg:** 28’s, 30’s	
446	**90 mg:** 7’s, 28’s, 30’s	
447	**120 mg:** 7’s, 28’s, 30’s	
448	Not all pack sizes may be marketed.	
449		

450	~~**Registration numbers/reference numbers**~~	Moved below
451	~~**MARACOXA 60:** 49/3.1/0588~~	
452	~~**MARACOXA 90:** 49/3.1/0589~~	
453	~~**MARACOXA 120:** 49/3.1/0590~~	
454		
455	**Holder of Certificate of Registration ~~and Manufacturer~~**	PIL guideline
456	Viatris South Africa (Pty) Ltd	
457	4 Brewery Street	
458	Isando, Johannesburg, 1600	
459	Republic of South Africa	
460		
461	~~**Date of publication**~~ **This leaflet was last revised in**	PIL guideline
462	~~Date of publication: 12 May 2020~~	
463	~~Date of revision of text: 16 January 2024~~	
464	<u>To be confirmed</u>	
465		
466	**Registration numbers~~/reference numbers~~**	PIL guideline
467	**MARACOXA 60:** 49/3.1/0588	
468	**MARACOXA 90:** 49/3.1/0589	
469	**MARACOXA 120:** 49/3.1/0590	