



IMPORTANT MEDICINE SAFETY INFORMATION

RECOMMENDED CALCULATION OF CONTRACEPTION DURATION AFTER COMPLETION OF THERAPY TO MINIMISE THE RISK OF GENOTOXIC ANTICANCER MEDICINE-MEDIATED REPRODUCTIVE ADVERSE EVENTS

12 April 2024

Dear Healthcare Professional,

In collaboration with the South African Health Products Regulatory Authority (SAHPRA), the companies listed above would like to inform you about recommended calculations of contraception duration after completion of therapy with genotoxic anticancer medicines (Including potential genotoxic metabolites).

Summary

- The risk of genotoxic anticancer medicines (and their potential genotoxic metabolites)-mediated reproductive adverse events including, embryotoxicity and teratogenicity has been identified.
- To minimise embryofoetal developmental risk while receiving and after completion of therapy with genotoxic anticancer medicines, new calculations for contraception is recommended in female patients receiving the genotoxic anticancer medicines and to female sexual partners of male patients receiving the genotoxic pharmaceuticals.

Background on the safety concern

Due to their genotoxic nature, anti-cancer therapies, may cause spontaneous abortions, infertility or heritable damage to the offspring and possibly to the subsequent generations. In males, genotoxic products may cause DNA damage in the sperm, potentially resulting in adverse events in the embryo or foetus of a female sexual partner. In females, genotoxic products may directly affect the embryo or foetus or may cause DNA damage in the oocytes.

To minimise the risk of drug-induced heritable DNA damage and to ensure that genomic integrity of gametes at the time of conception is maintained, patients are generally advised to use highly effective contraception during treatment and for an adequate period of time following the end of treatment with genotoxic medicines.

The Professional Information (PI) and Patient Information Leaflet (PIL) of genotoxic anticancer medicines listed below will be updated to appropriately reflect the above safety information.

Advice to healthcare professionals

- Male patients should be advised to use highly effective contraception, until the end of relevant systemic exposure to the genotoxic compound including potential genotoxic metabolites (i.e. five half-lives after the last dose) plus 90 days (i.e., 60-75 days for sperm production plus 10-14 days for the transport to epididymis).
- Female patients and female sexual partners of male patients receiving genotoxic anticancer medicines, should be advised to use highly effective contraception, until the end of relevant systemic exposure to the genotoxic compound including potential genotoxic metabolites (i.e. five half-lives after the last dose) plus 6 months (which covers the growth and maturation phase of folliculogenesis).
- Healthcare professionals are urged to report any adverse drug reactions (ADRs) or product quality problems associated with the use of the products listed below to their respective companies, or to SAHPRA via the following eReporting link <https://primaryreporting.who-umc.org/ZA> available on the SAHPRA website (www.sahpra.org.za)
- Alternatively, please complete the ADR reporting form accessible via the SAHPRA website at <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/> and email it to adr@sahpra.org.za.
- Additionally, reporting can be done via the Med Safety App. The App can be downloaded into a smart mobile phone through Google Play or App store. For more information on Med Safety App, please use the following link <https://medsafety.sahpra.org.za/>.
- For more information on ADR reporting of products listed below, please contact the SAHPRA Pharmacovigilance unit at pvqueries@sahpra.org.za or alternatively use the contact details indicated below

Company contact points

COMPANY	PRODUCT	ACTIVE INGREDIENT	REG NO	Contact details
Zydus Healthcare SA (Pty) LTD	Rogem 1	Gemcitabine 1.0 g	A46/26/0103	Madhu B Swarna medicinesafety@zydus.co.za Ph: 066 474 3574
	Rogem 200	Gemcitabine 200,0mg	A46/26/0104	
	Gemcitabine Zydus 1g	Gemcitabine 1.0 g	A46/26/0105	
	Gemcitabine 200mg	Gemcitabine 200,0mg	A46/26/0106	
	Taxocan 20	Docetaxel 20mg	A46/26/0265	
	Taxocan 80	Docetaxel 80mg	A46/26/0264	
	Docetaxel Zydus 20	Docetaxel 20mg	A46/26/0263	
	Docetaxel Zydus 80	Docetaxel 80mg	A46/26/0262	
	Castra 1	Anastrozole 1mg	A42/21.12/0995	
Accord Healthcare	Accoran	Busulfan	52/26/1000	Bashier Surve bashier@accordhealth.co.za Cell: 0827864747
	Accord Epirubicin 10	Epirubicin	42/26/0153	
	Accord Epirubicin 50	Epirubicin	42/26/0900	
	Epicord 10	Epirubicin	42/26/0152	
	Epicord 50	Epirubicin	42/26/0997	
	Accord Irinotecan 40	Irinotecan	41/26/1004	
	Accord Irinotecan 100	Irinotecan	44/26/0025	
	Docetaxel Accord 20	Docetaxel	49/26/0832	
	Docetaxel Accord 80	Docetaxel	49/26/0833	
	Docetaxel Accord 100	Docetaxel	49/26/0834	
	Cabitas	Cabazitaxel	51/26/0326,325	
	Capexa 150 mg	Capecitabine	49/26/0683	
	Capexa 500 mg	Capecitabine	49/26/0684	
	Imatinib Accord 100 mg	Imatinib	49/26/0740	
	Imatinib Accord 400 mg	Imatinib	49/26/0741	
	Pemetrexed Accord 500	Pemetrexed	49/26/0888	
	Pemetrexed Accord 100	Pemetrexed	52/26/1002	
	Terexta 500	Pemetrexed	49/26/0889	
	Terexta 100	Pemetrexed	52/26/1003	
	Pemetrexed Solution 100 mg/4 ml	Pemetrexed	55/26/0377	
	Pemetrexed Solution 500 mg/20 ml	Pemetrexed	55/26/0378	
	Pemetrexed Solution 850 mg/34 ml	Pemetrexed	55/26/0379	
	Pemetrexed Solution 1000 mg/40 ml	Pemetrexed	55/26/0380	
	Oplaxin 50 mg	Oxaliplatin	46/26/0212	
	Oplaxin 100 mg	Oxaliplatin	46/26/0213	
	Accord Paclitaxel 30	Paclitaxel	44/26/0377	
	Accord Paclitaxel 100	Paclitaxel	44/26/0378	
	Accord Paclitaxel 300	Paclitaxel	44/26/0379	
	Cisacor 10	Cisplatin	43/26/1019	
	Cisacor 50	Cisplatin	43/26/1021	
	Doxorubicin Accord 10 mg/5 ml	Doxorubicin	46/26/0484	
	Doxorubicin Accord 50 mg/25 ml	Doxorubicin	46/26/0485	

	Doxorubicin Accord 200 mg/100 ml	Doxorubicin	46/26/0486	
	Rubexet 10 mg/5 ml	Doxorubicin	46/26/0487	
	Rubexet 50 mg/25 ml	Doxorubicin	46/26/0488	
	Rubexet 200 mg/100 ml	Doxorubicin	46/26/0489	
	Accord Vincristine 1 mg/ml	Vincristine	41/26/1002	
	Accord Temozolomide 5	Temozolomide	44/26/0960	
	Accord Temozolomide 10	Temozolomide	44/26/0961	
	Accord Temozolomide 100	Temozolomide	44/26/0962	
	Accord Temozolomide 250	Temozolomide	44/26/0963	
	Accord Gemcitabine 200 mg	Gemcitabine	42/26/0088	
	Accord Gemcitabine 1 g	Gemcitabine	42/26/0903	
Teva Pharmaceuticals (PTY) Ltd	Abic Vincristine 1 mg/ml	Vincristine	T/26/221	Safety.South-Africa@teva.co.il Tel: 011 055 0200 Fax: 011 388 2688
	Abic Vincristine 2 mg/2 ml	Vincristine	W/26/241	
	Abitrexate 2,5 mg	Methotrexate	37/26/0466	
	Abitrexate 5 g/50 ml	Methotrexate	W/26/386	
	Abitrexate 50 mg/2 ml	Methotrexate	T/26/63	
	Abitrexate 500 mg/20 ml	Methotrexate	T/26/64	
	Abitrexate 1000 mg/10 ml	Methotrexate	T/26/57	
	Carbosin 150 mg/15 ml	Carboplatin	Z/26/261	
	Carbosin 450 mg/45 ml	Carboplatin	Z/26/262	
	Carbosin 600 mg/60 ml	Carboplatin	A39/26/0170	
	Docetaxel 20 Teva	Docetaxel	47/26/0940	
	Docetaxel 80 Teva	Docetaxel	47/26/0941	
	Doxorubicin-Sol PCH 10 mg	Doxorubicin	Z/26/167	
	Doxorubicin-Sol PCH 50 mg	Doxorubicin	Z/26/169	
	Dasatinib 20 Teva	Dasatinib	55/26/0448	
	Dasatinib 50 Teva	Dasatinib	55/26/0449	
	Dasatinib 70 Teva	Dasatinib	55/26/0450	
	Dasatinib 100 Teva	Dasatinib	55/26/0451	
	Eposin 100 mg/5 ml	Etoposide	32/26/0263	
	Fluracedyl 500 mg/10 ml	Fluorouracil	35/26/0349	
	Fluracedyl 1000 mg/20 ml	Fluorouracil	35/26/0350	
	Fluracedyl 5000 mg/20 ml	Fluorouracil	35/26/0351	
	Oxaliplatin PCH 50 mg/10 ml	Oxaliplatin	43/26/0102	
	Oxaliplatin PCH 100 mg/20 ml	Oxaliplatin	43/26/0103	
	PCH-Paclitaxel 30 mg/5 ml	Paclitaxel	A40/26/0609	
	PCH-Paclitaxel 100 mg/16.7 ml	Paclitaxel	A40/26/0610	
PCH-Paclitaxel 300 mg/50 ml	Paclitaxel	A40/26/0611		
Tamoplex 20 mg	Tamoxifen	34/21.12/0067		
Teva Fludarabine 50 mg/2ml	Fludarabine	43/26/0009		
Vinblastine Teva 10	Vinblastine	45/26/0373		
Lamar International (Pty) Ltd	Pemject	Pemetrexed	51/26/1066	Annika Neethling annika.neethling@lamar.co.za

Forrester Pharma (Pty) Ltd	Mylomid 10	Lenalidomide 10 mg	54/32/0730.716	Naazneen Chilwan naazneen@forresterpharma.com pv@forresterpharma.com	
	Mylomid 25	Lenalidomide 25 mg	54/32/0733.719		
Eurolab (Pty) Ltd	Miblex 3,5 mg	Bortezomib	50/26/0093	Melani Hendricks melani@eurolab.co.za +27 83 414 2313	
	Vexfan	Busulfan	55/26/0347		
	Pecaset 150 mg	Capecitabine	49/26/0681		
	Pecaset 500 mg	Capecitabine	49/26/0682		
	Eurotax 20 mg	Docetaxel	52/26/0263		
	Eurotax 80 mg	Docetaxel	52/26/0264		
	Enzutix 40 mg	Enzalutamide	55/26/0125		
	Tarpib 25 mg	Erlotinib HCl	52/26/0773		
	Tarpib 100 mg	Erlotinib HCl	52/26/0774		
	Tarpib 150 mg	Erlotinib HCl	52/26/0775		
	Gefirix 250 mg	Gefitinib	55/26/0115		
	Cytigem 200 mg	Gemcitabine	42/26/0089		
	Cytigem 1 g	Gemcitabine	42/26/0902		
	Mivesta 100 mg	Imatinib	49/26/0742		
	Mivesta 400 mg	Imatinib	49/26/0743		
	Irinotas 100 mg	Irinotecan HCl	44/26/0024		
	Irinotas 400 mg	Irinotecan HCl	41/26/1003		
	Eurolen 5 mg	Lenalidomide	53/32/0739		Nicky Holl drug-safety@eurolab.co.za +27 83 309 7816
	Eurolen 10 mg	Lenalidomide	53/32/0740		
	Eurolen 15 mg	Lenalidomide	53/32/0741		
	Eurolen 25 mg	Lenalidomide	53/32/0742		
	Oxilico 50 mg	Oxaliplatin	51/26/1096		
	Oxilico 100 mg	Oxaliplatin	51/26/1097		
	Intas Oxaliplatin 50	Oxaliplatin	44/26/0380		
	Intas Oxaliplatin 100	Oxaliplatin	42/26/1066		
	Paclitaxel 30 Eurolab	Paclitaxel	44/26/0374		
	Paclitaxel 100 Eurolab	Paclitaxel	44/26/0375		
	Paclitaxel 300 Eurolab	Paclitaxel	44/26/0376		
	Pomaxel 1 mg	Pomalidomide	56/32/0721		
	Pomaxel 2 mg	Pomalidomide	56/32/0722		
	Pomaxel 3 mg	Pomalidomide	56/32/0723		
	Pomaxel 4 mg	Pomalidomide	56/32/0724		
	Eurostib 200 mg	Sorafenib	55/26/0120		
	Tisumor 12,5 mg	Sunitinib	55/26/0238		
	Tisumor 25 mg	Sunitinib	55/26/0239		
	Tisumor 37,5 mg	Sunitinib	55/26/0240		
	Tisumor 50 mg	Sunitinib	55/26/0241		
	Temintas 5 mg	Temozolomide	44/26/0964		
	Temintas 20 mg	Temozolomide	44/26/0965		
	Temintas 100 mg	Temozolomide	44/26/0966		
Temintas 250 mg	Temozolomide	44/26/0967			
Navilin 20 mg	Vinorelbine	53/26/0743			
Navilin 30 mg	Vinorelbine	53/26/0744			

Adven Pharma (Pty) Ltd	Extreda 100	Pemetrexed	51/26/0516	Vinita Koen info@advenpharma.co.za
	Extreda 500	Pemetrexed	51/26/0517	Nicky Holl (PV lead) info@advenpharma.co.za +27 83 309 7816
Oethmaan Biosims (Pty) Ltd	Anamast 1 mg	Anastrozole	43/21.12/0074	Yusuf Ismail ga@oethmaan.co.za 011 433 0602
	Cisplatin 10mg/ 20ml Oethmaan	Cisplatin	37/25/0523	
	Cisplatin 50mg/ 100ml Oethmaan	Cisplatin	37/25/0524	
	Gemcitabine 1 g Oethmaan	Gemcitabine Hydrochloride	41/26/0489	
	Gemcitabine 200 mg Oethmaan	Gemcitabine Hydrochloride	41/26/0490	
	HX Etoposide 1000mg/50ml	Etoposide	37/26/0178	
	HX Etoposide 100mg/5ml	Etoposide	37/26/0175	
	HX Etoposide 200mg/10ml	Etoposide	37/26/0176	
	HX Etoposide 400mg/20ml	Etoposide	37/26/0177	
	HX Etoposide 50mg/2.5ml	Etoposide	37/26/0174	
	Doxred 10mg/5ml	Doxorubicin Hydrochloride	37/26/0030	
	Doxred 50 mg/25 ml	Doxorubicin Hydrochloride	37/26/0031	
	HX-Epirubicin 100mg/50ml	Epirubicin Hydrochloride	37/26/0389	
	HX-Epirubicin 10mg/5ml	Epirubicin Hydrochloride	37/26/0387	
	HX-Epirubicin 200mg/100ml	Epirubicin Hydrochloride	37/26/0390	
	HX-Epirubicin 50mg/25ml	Epirubicin Hydrochloride	37/26/0388	
	Loxat 100 - Infusion	Paclitaxil	41/26/1096	
	Loxat 30 - Infusion	Paclitaxil	41/26/1095	
	Loxat 300 - Infusion	Paclitaxil	41/26/1097	
	Irinotecan 100 Oethmaan	Irinotecan Hydrochloride	41/26/0029	
Irinotecan 40 Oethmaan	Irinotecan Hydrochloride	41/26/0028		
Adcock Ingram Limited	Baximo 25mg	Bendamustine hydrochloride monohydrate	53/26/0304	adcock.aereports@adcock.com Tel: +27 11 635 0134 Safety No :+27 73 540 7052
	Baximo 100mg	Bendamustine hydrochloride monohydrate	53/26/0305	

Adcock Ingram Critical Care	Docetaxel Adco 20 mg/1 ml	Docetaxel	46/26/0375	adcock.aereports@adcock.com Tel: +27 11 635 0134 Safety No: +27 73 540 7052
	Docetaxel Adco 80 mg/4 ml	Docetaxel	46/26/0376	
	Cabazitaxel Adco	Cabazitaxel	53/26/0360	
	Femzole 2.5	Letrozole	43/21.12/0734	
VIATRIS Healthcare (Pty) Ltd	Tezmyl 20 mg	Temozolomide	52/26/1007	Ansie Savrda +27 011 451 3000 +27 082 442 8557
	Tezmyl 100 mg	Temozolomide	50/26/1063	
	Tezmyl 250 mg	Temozolomide	52/26/1009	
	Efudix Ointment	5-Fluorouracil	D/13.8/122	
	Bendamustine 100 mg, 25 mg Mylan Inj.	Bendamustine	50/26/1063	
	Fulvestrant Mylan	Fulvestrant	50/26/1062	
	Medroxyprogesterone Mylan	Medroxyprogesterone	52/21.8.2/0992.991	
	Mytricon	Medroxyprogesterone	52/21.8.2/0991	
	Ogivri 150	Trastuzumab	52/26/0215.213	
	Ogivri 400	Trastuzumab	52/26/0215.214	
	Dronamyl 4 mg/5 ml Inj	Zoledronic Acid	47/32.2/0039	
VIATRIS South Africa (Pty)Ltd	Abevmy 100 mg	Bevacizumab	55/26/0256	Pranesh Ramadene +27 011 451 3000 +27 82 789 3065
	Abevmy 400 mg	Bevacizumab	55/26/0257	
	Bevamy 100 mg	Bevacizumab	55/26/0260.256	
	Bevamy 400 mg	Bevacizumab	55/26/0260.257	
	Ercyta 100	Erlotinib	51/26/0127	
	Ercyta 150	Erlotinib	51/26/0128	
	Mylan Irinotecan 100mg/5ml Inj.	Irinotecan	43/26/0348	
	Mylan Irinotecan 40 mg/2 ml Inj.	Irinotecan	43/26/0349	
	Methylprednisolone 1000 Viatris	Methylprednisolone	42/21.5.1/0312	
	Methylprednisolone 120 Viatris	Methylprednisolone	42/21.5.1/0310	
	Paclitaxel 100 Viatris (Mylan)	Paclitaxel	42/26/0658	
	Paclitaxel 30 Viatris (Mylan)	Paclitaxel	42/26/0657	
	Paclitaxel 300 Viatris (Mylan)	Paclitaxel	42/26/0659	
	Juno Pharma SA	Valoma 1	Bortezomib	
Valoma 2,5		Bortezomib	54/26/0345	
Valoma 3,5		Bortezomib	54/26/0346	
Cipla Medpro (Pty) Ltd	Oncogem 1000	Gemcitabine 1000 mg	43/26/1172	Praba Thandring Praba.Thandring@Cipla.com drugsafetysa@cipla.com Tel: 021 943 4200
	Oncogem 200	Gemcitabine 200 mg	43/26/1171	
	Cipla Cytarabine Injection 100 mg (1 ml)	Cytarabine	A39/26/0452	
	Cipla Cytarabine Injection 100 mg (5ml)	Cytarabine	A39/26/0453	
	Cipla Cytarabine Injection 100 mg (10ml)	Cytarabine	A39/26/0454	
	Cipla Doxorubicin 10	Doxorubicin	41/26/0034	
	Cipla Doxorubicin 50	Doxorubicin	41/26/0034	

	Bleopcip	Bleomycin	45/26/0184	
	Cipla Bleomycin	Bleomycin	45/26/0185	
	Oxaliplatin 50	Oxaliplatin	46/26/0477	
	Oxaliplatin 100	Oxaliplatin	46/26/0478	
	Cipla-Oxiplatin 50	Oxaliplatin	47/26/1106	
	Cipla-Oxiplatin 100	Oxaliplatin	47/26/1107	
	Fluoroplex	Fluorouracil	45/26/0210	
	Cipla Fluorouracil	Fluorouracil	45/26/0211	
	Cipla Irinotecan 40 mg/ml	Irotectan	41/26/0049	
	Cipla Irinotecan 100 mg/5 ml	Irotectan	41/26/0050	
	Cipla Paclitaxel 30 mg/5 ml	Paclitaxel	41/26/0423	
	Cipla Paclitaxel 100 mg/16,7 ml	Paclitaxel	41/26/0424	
	Cipla Paclitaxel 300 mg/ 50 ml	Paclitaxel	41/26/0425	
	Cipla-Topotecan 1 mg	Topotecan	43/26/0006	
	Cipla-Topotecan 4 mg	Topotecan	43/26/0007	
	Cipla Vinorelbine 10	Vinorelbine	42/26/0083	
	Cipla Vinorelbine 50	Vinorelbine	42/26/0084	
	Immunucept	Mycophenolate mofetil	45/32.2/1078	
	Kemocarb 150	Carboplatin	A38/26/0532	
	Kemocarb 450	Carboplatin	A38/26/0533	
Ranbaxy Pharmaceuticals (pty)Ltd	Caxeta 150	Capecitabine	47/26/1287	
	Caxeta 500	Capecitabine	47/26/1288	
	Gemtaz 1g	Gemcitabine	41/26/0933	
	Gemtaz 200 mg	Gemcitabine	41/26/0934	
	Dasamia 20	Dasatinib	560207	
	Dasamia 50	Dasatinib	560208	
	Dasamia 70	Dasatinib	560209	
	Dasamia 100	Dasatinib	560210	
	Sunmatin 100	imatinib	44/26/0886	
	Sunmatin 400	imatinib	44/26/0887	
	Doxolip	Doxorubicin	43/26/0018	
	Botigen 3,5	Bortezomib	51/26/0163	
	Pexitaz 200	pemetrexed	51/26/0231	
	Pexitaz 500	pemetrexed	51/26/0232	
	Gemtaz 1300 mg/130 ml RTU	Gemcitabine	54/26/0843	
	Gemtaz 1400 mg/140 ml RTU	Gemcitabine	54/26/0844	
	Gemtaz 1500 mg/150 ml RTU	Gemcitabine	54/26/0845	
	Gemtaz 1600 mg/160 ml RTU	Gemcitabine	54/26/0846	
	Gemtaz 1700 mg/170 ml RTU	Gemcitabine	54/26/0847	
	Gemtaz 1800 mg/180 ml RTU	Gemcitabine	54/26/0848	
	Gemtaz 1900 mg/190 ml RTU	Gemcitabine	54/26/0849	

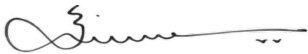

Geeta Ghela
Geeta.Ghela@sunpharma.com

	Gemtaz 1300 mg/130 ml RTU	Gemcitabine	54/26/0843	
	Gemtaz 2000 mg/200 ml RTU	Gemcitabine	54/26/0850	
	Gemtaz 2200 mg/220 ml RTU	Gemcitabine	54/26/0851	
Baxter Healthcare South Africa (Pty) Ltd	Caelyx 2mg/ml	Doxorubicin HCl	32/26/0533	Shivani Patel Responsible Pharmacist Tel: 011 790 2000 Mobile: 066 586 7379 Drug_Safety_MEA@baxter.com
Aspen Pharmacare	Mitomycin-C injection 10 mg (section 36)	Mitomycin	R/26/48	Tel: +27 800 118 088 Fax: +27 11 239 6306 drugsafety@aspenpharma.com
	Myleran 2 mg tablets	Busulfan	H2750 (Act 101/1965)	
	Leukeran 2 mg tablets	Chlorambucil	H2747 (Act 101/1965)	
	Alkeran 2 mg tablets	Melphalan	H/26/2744	
	Alkeran 50 powder and solvent for solution for injection/infusion	Melphalan	27/26/0506	
	Imuran 50mg tablets	Azathioprine	D/26/98	
	Lanvis 40 mg tablets	Tioguanine	C/26/119	
	Puri-Nethol 50 mg tablets	Mercaptopurine	H2751 (Act 101/1965)	
Aurogen South Africa (Pty) Ltd	AMITRAZ	Anastrozole	54/21.12/0163.162	Samantha Pillay Chengiah pv.za@aurobindo.com
	OMUBEN 100 mg	Bendamustine hydrochloride	55/26/0658.656	
	OMUBEN 25 mg	Bendamustine hydrochloride	55/26/0657.655	
	BETANUZ	Bortezomib	54/26/0081	
	AUOXEDA 150 mg	Capecitabine	53/26/0100	
	AUOXEDA 500 mg	Capecitabine	53/26/0101	
	DARBECT	Decitabine	55/26/0173.172	
	VESOTA	Fulvestrant	56/26/0406.405	
	INOTRIX 100 mg/2 ml	Irinotecan hydrochloride trihydrate	55/26/0363	
	INOTRIX 300 mg/2 ml	Irinotecan hydrochloride trihydrate	55/26/0364	
	INOTRIX 40 mg/2 ml	Irinotecan hydrochloride trihydrate	55/26/0362	
	CANCALID 2,5 mg	Lenalidomide	56/32/0518.511	
	CANCALID 5 mg	Lenalidomide	56/32/0519.512	
	CANCALID 7,5 mg	Lenalidomide	56/32/0520.513	


	CANCALID 10 mg	Lenalidomide	56/32/0521.514	
	CANCALID 15 mg	Lenalidomide	56/32/0522.515	
	CANCALID 20 mg	Lenalidomide	56/32/0523.516	
	CANCALID 25 mg	Lenalidomide	56/32/0524.517	
	ROZILAT	Letrozole	55/21.12/0204	
	PRELAUD	Leuprolide acetate	54/21.10/0090.089	
	ZALCAREN AND STERILE DILUENT FOR ZALCAREN	Melphalan hydrochloride	54/26/0597.596	
	XILAZ 100 mg/20 ml	Oxaliplatin	56/26/0777.774	
	XILAZ 200 mg/40 ml	Oxaliplatin	56/26/0778.775	
	XILAZ 50 mg/10 ml	Oxaliplatin	56/26/0776.773	
	PLEDITEX	Plerixafor	55//32.2/0214.213	
	TREMOFID	Tamoxifen citrate	56/21.12/0698	
Fresenius Kabi South Africa (Pty) Ltd	Busulfan 6 mg/ml Fresenius	Busulfan	49/26/0087	Safety.fksa@fresenius-kabi.com Tel: 082 606 4786
	Carboplatin 50 mg/5 ml Fresenius	Carboplatin	48/26/0254	
	Carboplatin 150 mg/15 ml Fresenius	Carboplatin	48/26/0255	
	Carboplatin 450 mg/45 ml Fresenius	Carboplatin	48/26/0256	
	Carboplatin 600 mg/60 ml Fresenius	Carboplatin	48/26/0257	
	Cytarabine 100 mg/1 ml Fresenius	Cytarabine	49/26/0043	
	Cytarabine 500 mg/5 ml Fresenius	Cytarabine	49/26/0044	
	Cytarabine 1 g/10 ml Fresenius	Cytarabine	49/26/0045	
	Cytarabine 2 g/20 ml Fresenius	Cytarabine	49/26/0046	
	Docetaxel 20 mg/1 ml Fresenius	Docetaxel	48/26/0667	
	Docetaxel 80 mg/4 ml Fresenius	Docetaxel	48/26/0668	
	Doxorubicin 2 mg/ml (10 mg/5 ml) Fresenius	Doxorubicin	48/26/0937	
	Doxorubicin 2 mg/ml (50 mg/25 ml) Fresenius	Doxorubicin	48/26/0938	
	Etoposide 100 mg/5 ml Fresenius	Etoposide	47/26/1174	
	Etoposide 200mg/10 ml Fresenius	Etoposide	47/26/1175	
	Etoposide 500 mg/25 ml Fresenius	Etoposide	47/26/1176	
	Etoposide 1000 mg/50 ml Fresenius	Etoposide	47/26/1177	
	Gemcitabine 200 mg RTU Fresenius	Gemcitabine	50/26/0871	
	Gemcitabine 1 g RTU Fresenius	Gemcitabine	50/26/0872	
	Gemcitabine 2 g RTU Fresenius	Gemcitabine	50/26/0874	
Irinotecan 40 mg/2 ml FKSA	Irinotecan	45/26/0915		
Irinotecan 100 mg/5 ml FKSA	Irinotecan	45/26/0916		

	Irinotecan 300 mg/15 ml FKSA	Irinotecan	45/26/0917	
	Irinotecan 500 mg/25 ml FKSA	Irinotecan	45/26/0918	
	Oxaliplatin 50 mg/10 ml Fresenius	Oxaliplatin	46/26/0897	
	Oxaliplatin 100 mg/20 ml Fresenius	Oxaliplatin	46/26/0898	
	Paclitaxel 30 mg/5 ml Fresenius	Paclitaxel	43/26/0237	
	Paclitaxel 100 mg/16,7 ml Fresenius	Paclitaxel	43/26/0244	
	Paclitaxel 300 mg/50 ml Fresenius	Paclitaxel	43/26/0239	
Acino Pharma (Pty) Ltd	Azamun 50 MG	azathioprine	36/26/0006	Shaistha Sing Responsible Pharmacist Shaistha.Sing@acino.swiss
Sandoz South Africa (Pty) Ltd	Gemcitabine Sandoz	Gemcitabine	45/26/1159	patient.safety.sac@sandoz.com Tel: +27 (11) 347 6600
	Mitoxantrone HEXAL 20 mg/10 ml	Mitoxantrone	37/26/0168	
	Mycocept 250	Mycophenolate mofetil	41/34/0815	
	Eloplat 50	Oxaliplatin	46/26/0919	
	Eloplat 100	Oxaliplatin	46/26/0920	
	Eloplat 150	Oxaliplatin	46/26/0921	
	Eloplat 200	Oxaliplatin	46/26/0922	
	Hycamtin 0,25 mg	Topotecan hydrochloride	42/26/0739	
	Hycamtin 1 mg	Topotecan hydrochloride	42/26/0740	
	Hycamtin 4 mg	Topotecan hydrochloride	31/26/0300	
	Sandoz Vinorelbine 10 mg/1 ml IVI	Vinorelbine tartrate	42/26/0132	
	Sandoz Vinorelbine 50 mg/5 ml IVI	Vinorelbine tartrate	42/26/0133	
	Prosaglic 20 & Prosaglic 80	Docetaxel	46/26/0176 & 46/26/0177	

Yours Sincerely,

Madhu Babu Swarna Responsible Pharmacist Zydus Healthcare SA (Pty) LTD Signature: 	Salomie Keyser Responsible Pharmacist Teva Pharmaceuticals (PTY) Ltd Signature: Salomie Keyser Digitally signed by Salomie Keyser Date: 2024.03.13 14:37:53 +02'00'	Naazneen Chilwan Responsible Pharmacist Lamar International (Pty) Ltd Signature: 
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<p>Bashier Surve Responsible Pharmacist & Regulatory Affairs Manager Accord Healthcare Signature:</p>  <p>14/03/2024</p>	<p>Fatima Booysen Responsible Pharmacist Forrester Pharma (Pty) Ltd Signature:</p> 	<p>Melani Hendricks Responsible Pharmacist Eurolab (Pty) Ltd.</p>  <p>14/03/2023</p>
<p>Vinita Koen Responsible Pharmacist Adven Pharma (Pty) Ltd. Signature:</p> 	<p>Yusuf Ismail QA Manager/ PV Officer Oethmaan Biosims (Pty) Ltd Signature:</p> <p>Yusuf Ismail</p> <p>Digitally signed by Yusuf Ismail DN: cn=Yusuf Ismail, o=Oethmaan Biosims Pty Ltd, ou=Quality Assurance Manager, email=qa@oethaan.co.za, c=ZA Date: 2024.03.18 09:14:46 +02'00'</p>	<p>Tammy Chetty Responsible Pharmacist Adcock Ingram Limited Signature:</p> <p>Tammy Chetty</p> <p>Digitally signed by Tammy Chetty Date: 2024.03.15 11:06:54 +02'00'</p>
<p>Lucelle Iyer Responsible Pharmacist Adcock Ingram Critical Care</p> <p>Signature:</p> <p>Lucelle</p> <p>Digitally signed by Lucelle Date: 2024.03.15 11:12:24 +02'00'</p>	<p>Ansie Savrda Viatrix Healthcare (Pty) Ltd 4 Brewery Street Isando</p> <p>Signature:</p> <p>Ansie Savrda</p> <p>Digitally signed by Ansie Savrda Date: 2024.03.15 10:08:28 +02'00'</p>	<p>Pranesh Ramadene Viatrix South Africa (Pty) Ltd 4 Brewery Street Isando</p> <p>Signature:</p> <p>Ramadene</p> <p>Digitally signed by Pranesh Ramadene Date: 2024.03.15 10:05:42 +02'00'</p>
<p>Tsiane Makou Responsible Pharmacist Juno Pharma SA Tsiane.Makou@Junopharma.co.za</p> <p>Signature:</p> <p>Tsiane Makou</p> <p>Digitally signed by Tsiane Makou Date: 2024.03.15 14:46:48 +02'00'</p>	<p>Indirani Govender Responsible Pharmacist Sandoz South Africa (Pty) Ltd Indirani.govender@sandoz.com patient.safety.sac@sandoz.com</p> <p>Signature:</p> <p>Govender Indirani</p> <p>Digitally signed by Govender Indirani DN: dc=com, ou=ranbaxy, ou=people, ou=GX, serialNumber=1993355, cn=Govender Indirani Reason: I attest to the accuracy and integrity of this document. Date: 2024.03.15 15:48:58 +02'00'</p>	<p>Geeta Ghela Responsible Pharmacist Ranbaxy Pharmaceuticals (pty) Ltd Geeta.Ghela@sunpharma.com</p> <p>Signature:</p> <p>Geeta Ghela</p> <p>Digitally signed by Geeta Ghela DN: cn=Geeta Ghela, o=Responsible Pharmacist, ou=Ranbaxy Pharmaceuticals(pty)ltd, email=Geeta.Ghela@sunpharma.com, c=ZA Date: 2024.03.18 08:05:24 +02'00'</p>

<p>Praba Thandrind Responsible Pharmacist Cipla Medpro (Pty) Ltd Praba.Thandrind@Cipla.com drugsafetysa@cipla.com Signature:</p>	<p>Shivani Patel Responsible Pharmacist Baxter Healthcare South Africa (Pty) Ltd Tel: 011 790 2000 Mobile: 066 586 7379 Email: Drug_Safety_MEA@baxter.com Signature:</p> <p>SHIVANI PATEL</p> <p>Digitally signed by: SHIVANI PATEL DN: CN = SHIVANI PATEL OU = EU, United Arab Emirates, Users, South Africa Date: 2024.03.18 10:12:15 +02'00'</p>	<p>Nikola Whelan Responsible Pharmacist Aspen Pharmacare drugsafety@aspenpharma.com Signature:</p> <p>Nikola Whelan</p> <p>Digitally signed by Nikola Whelan Date: 2024.03.18 11:04:29 +02'00'</p>
<p>Samantha Pillay Chengiah Responsible Pharmacist & RA Manager Aurogen South Africa (Pty) Ltd pv.za@aurobindo.com Signature:</p>  <p>Digitally signed by sam DN: C=SA, CN=sam, E=samantha.chengiah@aurobindo.com Reason: I am the author of this document Location: C:\Users\samantha\Pictures\Saved Pictures Date: 2024-03-18 11:14:26 Foxit PhantomPDF Version: 9.7.1</p>	<p>Sharon Davis Responsible Pharmacist / Head of Quality Fresenius Kabi South Africa (Pty) Ltd Safety.fksa@fresenius-kabi.com Signature:</p> <p>DocuSigned by: Sharon Davis 7A06D987E0754DF...</p> <p>3/18/2024 11:20 CET</p>	<p>Shaistha Sing Responsible Pharmacist Acino Pharma (Pty) Ltd Shaistha.Sing@acino.swiss Signature:</p> <p>p.p.</p> <p>18 March 2024</p>

References

1. U.S. Department of Health and Human Services; Food and Drug Administration; Center for Drug Evaluation and Research (2019) Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations. Guidance for Industry. Office of Communications, Food and Drug Administration, Silver Spring, MD, USA
2. European Medicines Agency (2023) SWP/NcWP recommendations on the duration of contraception following the end of treatment with a genotoxic drug European Medicines Agency, Amsterdam, The Netherlands; EMA/CHMP/SWP/74077/2020 rev. 1*
3. Suzuki, N., Takai, Y., Yonemura, M. *et al.* Guidance on the need for contraception related to use of pharmaceuticals: the Japan Agency for Medical Research and Development Study Group for providing information on the proper use of pharmaceuticals in patients with reproductive potential. *Int J Clin Oncol* **27**, 829–839 (2022). <https://doi.org/10.1007/s10147-022-02149-1>
4. Banholzer ML, Wandel C, Barrow P, Mannino M, Schmitt G, Guérard M, Müller L, Greig G, Amemiya K, Peck R, Singer T and Doessegger L. Clinical trial considerations on male contraception and collection of pregnancy information from female partner: update. *Clin Trans Med* 5:23, 2016. <https://doi.org/10.1186/s40169-016-0103-8>.