



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



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NOTICE: RECOMMENDED THERAPEUTIC ALTERNATIVE FOR DINOPROSTONE TABLETS

Circular no. 2 of February 2022

The Adult Hospital Level (2019 edition) and Paediatric Hospital Level (2017 edition) Standard Treatment Guidelines (STGs) and Essential Medicines Lists (EML) currently recommend the use of dinoprostone tablets. The contracted supplier of dinoprostone tablets, Pfizer has indicated that due to manufacturing constraints, there is a current supply interruption, which is expected to continue for an extended period.

As Pfizer is the sole supplier of dinoprostone tablets in South Africa, the therapeutic alternatives as listed in the respective STGs and EML are recommended for this period.

Until the supply of dinoprostone tablets normalises, the STGs and EML recommends the following therapeutic alternatives for the respective indications:

Indications: Adult Hospital Level (2019)	Current recommendation in STGs and EML	Therapeutic alternative
<p>• 6.15 Labour Induction Cervix unfavourable</p>	<p>Prostaglandins, e.g.:</p> <ul style="list-style-type: none"> • Dinoprostone gel, intravaginally, 1 mg. <ul style="list-style-type: none"> ○ Repeat after 6 hours. ○ Do not exceed 4 mg. <p>OR</p> <ul style="list-style-type: none"> • Dinoprostone tablets, intravaginally, 1 mg. <ul style="list-style-type: none"> ○ Repeat after 6 hours. ○ Do not exceed 4 mg. <p>OR</p> <ul style="list-style-type: none"> • Misoprostol, oral, 20 mcg 2 hourly until in labour, or up to 24 hours. <ul style="list-style-type: none"> ○ Oral misoprostol may be given as freshly made-up solution of one 200 mcg tablet in 200 mL water, i.e. 1 mcg/mL solution. Give 20 mL of this solution 2 hourly. ○ Stop misoprostol administration when in established labour. ○ Maximum 24 hours. ○ Never use oxytocin and misoprostol simultaneously. ○ Misoprostol and other prostaglandins are contraindicated in women with previous Caesarean sections and in grand multiparous women. 	<p>Prostaglandins, e.g.:</p> <ul style="list-style-type: none"> • Dinoprostone gel, intravaginally, 1 mg. <ul style="list-style-type: none"> ○ Repeat after 6 hours. ○ Do not exceed 4 mg. <p>OR</p> <ul style="list-style-type: none"> • Misoprostol, oral, 20 mcg 2 hourly until in labour, or up to 24 hours. <ul style="list-style-type: none"> ○ Oral misoprostol may be given as freshly made-up solution of one 200 mcg tablet in 200 mL water, i.e. 1 mcg/mL solution. Give 20 mL of this solution 2 hourly. ○ Stop misoprostol administration when in established labour. ○ Maximum 24 hours. ○ Never use oxytocin and misoprostol simultaneously. ○ Misoprostol and other prostaglandins are contraindicated in women with previous Caesarean sections and in grand multiparous women.

Indications: Paediatric Hospital Level (2017)	Current recommendation in STGs and EML	Therapeutic alternative
<ul style="list-style-type: none"> • 19.2 Cyanotic Heart Disease in the Newborn To keep ductus arteriosus open 	Prostaglandin therapy, i.e.: <ul style="list-style-type: none"> • Alprostadil, IV, 0.05–0.1 mcg/kg/minute, initial dose, (under specialist consultation). <ul style="list-style-type: none"> ○ Maintenance dose: 0.01–0.1 mcg/kg/minute. OR <ul style="list-style-type: none"> • Dinoprostone, via naso/orogastric tube, (under specialist consultation). <ul style="list-style-type: none"> ○ For babies < 2.5 kg: 0.125 mg 1–2 hourly (1/4 tablet suspended in 2 mL sterile water), or 50 mcg/kg/dose 1–2 hourly. ○ For babies > 2.5 kg: 0.25 mg hourly (½ tablet suspended in 2 mL water). 	Prostaglandin therapy, i.e.: <ul style="list-style-type: none"> • Alprostadil, IV, 0.05–0.1 mcg/kg/minute, initial dose, (under specialist consultation). <ul style="list-style-type: none"> ○ Maintenance dose: 0.01–0.1 mcg/kg/minute.

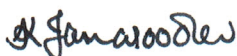
Procurement details of recommended alternatives:

NSN	Product	Supplier	Contract
189753544	Dinoprostone; 1mg/3g; Syringe, Prefilled; 3 g	Pfizer Laboratories (Pty) Ltd	HP08-2020SSP
180339642	Misoprostol; 200mcg; Tablet; 60 Tablets	Pfizer Laboratories (Pty) Ltd	HP03-2020CHM/01
180075498	Alprostadil; 500mcg/ml; injection; 1 ml	Pfizer Laboratories (Pty) Ltd	HP06-2021SVP

Supply status of the recommend alternatives has been confirmed.

Provinces and Healthcare Facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees. Kindly share with all healthcare professionals and relevant stakeholders.

Kind regards



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DIRECTOR: AFFORDABLE MEDICINES

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