MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

SCHEDULING MATTERS

RESCHEDULING OF DICLOFENAC

TO ALL APPLICANTS

Kindly be advised that at a recent meeting of the Medicines Control Council, Council resolved to reschedule diclofenac due to the potentially significant and life-threatening cardiovascular adverse effects, [1, 2, 3, 4, 5, 6] as follows:

Words in **[bold and in square brackets]** indicate omission from a Schedule

Words underlined with a solid line indicate insertions in a Schedule.

Schedule 1

Diclofenac,

a. when intended for application to the skin; (S3)

b. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

c. except when intended for the treatment of fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days.(S2)

Schedule 2

Diclofenac,

a. when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S3)

b. when intended for the treatment of **[post traumatic conditions]** fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days;

c. except when intended for application to the skin. (S1)

Schedule 3

Diclofenac,

a. except when intended for application to the skin; (S1) **[and]**

b. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)

c. except when intended for the treatment of **[post traumatic conditions]** fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days.(S2)

Please be advised that the office of the Registrar is in the process of drafting an amendment to the published Schedules, for consideration by the Minister of Health and publication in the Government *Gazette.*

Dr JC GOUWS
REGISTRAR OF MEDICINES

References

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3. Gislason, G. H., *et al*. (2009) 'Increased Mortality and Cardiovascular Morbidity Associated with use of Nonsteroidal Anti-inflammatory Drugs in Chronic Heart Failure', *Arch Inter Med*, 169(2), pp.141-149.

4. McGettigan, P., Henry, D. (No Date) 'Cardiac Risk with Non-Steroidal Anti-inflammatory Drugs: Systematic Review of Population-Based Controlled Observational Studies', *PLoS Med* 8/9, e1001098. Doi:10.1371/journal.pmed.1001098.

5. Rau, P.N., Knaus, E. (2008) 'Evolution of nonsteroidal anti-inflammatory drugs (NSAIDS): Cyclooxygenase inhibition and beyond', J Pharm Pharmaceut Sci, 11(2), pp. 81s-110s.

6. Rainsford, K.D. (2007) '*Anti-Inflammatory Drugs in the 21st Century* - INFLAMMATION IN THE PATHOGENESIS OF CHRONIC DISEASES: THE COX-2 CONTROVERSY', In: Harris, Randall E. (Editor) (*Subcellular Biochemistry Volume 42*). New York: Springer Science and Business Media Inc, pp. 3-27.