DEPARTMENT OF HEALTH
Republic of South Africa

SAHPRA
South African Health Products Regulatory Authority

SCHEDULING MATTERS

RESCHEDULING OF IBUPROFEN

TO ALL APPLICANTS

Kindly be advised that SAHPRA has resolved to reschedule ibuprofen, when intended for application to the skin and when indicated for the symptomatic relief of acute painful musculo-skeletal conditions caused by trauma such as sport injuries, sprains, strains and contusions, 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

Ibuprofen,

a. when contained in preparations intended for application to the skin, containing 1 % *m/m* or less of ibuprofen, and presented in a pack size exceeding 50 grams; (S0, S2, S3, S4).
b. when contained in oral medicinal preparations, intended for human use only, supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight. (S2, S3).
c. except when intended for veterinary use. (S3)

Schedule 2

Ibuprofen,

a. when contained in oral medicinal preparations, intended for human use only in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight. (S3)

b. when contained in oral medicinal preparations, intended for human use only as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S1, S3)

c. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)

d. except when contained in preparations intended for application to the skin, containing 1 % *m/m* or less of ibuprofen (S0, S1)

Schedule 3

Ibuprofen, except

a. when contained in preparations intended for application to the skin, containing 1 % *m/m* or less of ibuprofen (S0, S1)

b. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

c. when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

d. when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

e. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

f. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4)

Schedule 4

Ibuprofen,

a. when intended for the treatment of a haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age;

b. except when contained in preparations intended for application to the skin, containing 1 % *m/m* or less of ibuprofen (S0, S1)

c. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

d. except when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

e. except when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

f. except for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

g. except when intended for veterinary use. (S3)

Please be advised that SAHPRA 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.*

MS P NKAMBULE
ACTING CHIEF EXECUTIVE OFFICER