

Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette

No. 9714

Regulasiekoerant

Vol. 561

**Pretoria, 15 March
Maart 2012**

No. 35149

IMPORTANT NOTICE

The Government Printing Works will not be held responsible for faxed documents not received due to errors on the fax machine or faxes received which are unclear or incomplete. Please be advised that an "OK" slip, received from a fax machine, will not be accepted as proof that documents were received by the GPW for printing. If documents are faxed to the GPW it will be the sender's responsibility to phone and confirm that the documents were received in good order.

Furthermore the Government Printing Works will also not be held responsible for cancellations and amendments which have not been done on original documents received from clients.

CONTENTS • INHOUD

No.

Page
No. Gazette
 No.

GOVERNMENT NOTICE

Health, Department of

Government Notice

R. 227 Medicines and Related Substances Act (101/1965): Schedules 3 35149

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 227

15 March 2012

Schedule 0

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

SCHEDULES

The Minister of Health has, in terms of section 22A (2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), on the recommendation of the Medicines Control Council, made and updated the Schedules in the Schedule.

This Schedule amends the Schedules as published in Government Notice 1230 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Government Gazette 32838, 31 December 2009 using the following convention:

- Words in square brackets (e.g. **[Valerian]** in Schedule 1), indicate omission from a Schedule
- Words underlined with a solid line (e.g. Ambroxol in Schedule 1), indicate insertions in a Schedule.

SCHEDULE

In these Schedules, "the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Note: Where an alternative schedule(s) is included in natural parentheses at any point of an inscription, this is provided to indicate one or more alternative scheduling designation/s. This is for information only and shall not be used in the interpretation of such inscription.

SCHEDULE 1

Ambroxol.

Amorolfine.

Chloroform, preparations and mixtures containing more than 0.5 percent and less than 20 percent of chloroform, except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use. (S0, S5)

Ibuprofen

- a. when contained in preparations intended for application to the skin; (S2, S3, S4).
- 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

Schedule 1

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).

Nicotine, when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/24 hours. (S2, S3).

Zinc salts, **[when intended for veterinary use as an injection, except]**

- a. except when intended for oral ingestion, where the daily dose is less than 50 milligrams of elemental zinc[, **or when intended for topical use by humans**]; (S0), **[or]**
- b. except when intended for topical use by humans: (S0),
- c. when intended for veterinary use as an injection;
- d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

[Valerian]

- END SCHEDULE 1 -

SCHEDULE 2

[Amorolfine]

[Beclomethasone, when intended for nasal administration (other than by aerosol), in the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to a maximum dose equivalent to 100 micrograms of beclomethasone dipropionate per nostril, a maximum daily dose equivalent to 200 micrograms of beclomethasone dipropionate per nostril and a maximum of 200 doses per pack. (S3, S4)]

Beclomethasone dipropionate, when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- (a) a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril and
- (b) a maximum pack size of 200 doses. (S3, S4)

Schedule 2

Dextromethorphan.

[Flunisolide, when intended for nasal administration, other than by aerosol in a strength not exceeding 0,025 percent (m/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to-

- a. a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over the age of 16 years;
- b. a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in the case of children 12 to 16 years of age; and
- c. a pack size containing not more than 240 doses. (S3, S4)]

Flunisolide, when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, in a strength not exceeding 0,025 percent (m/v), and indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to-

- (a) a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over 16 years of age;
- (b) a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in children 12 to 16 years of age;
- (c) a maximum pack size of 240 doses. (S3, S4)

Fluticasone propionate, when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- (a) a maximum daily dose of 100 micrograms per nostril; and
- (b) a maximum pack size of 120 doses. (S3, S4)

Ibuprofen when contained in oral medicinal preparations

- a. containing ibuprofen 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. containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 ml 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

Schedule 2

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

Melatonin, when used for the amelioration of desynchronosis (jet-lag) in doses not exceeding 6mg daily. (S4).

Mometasone furoate, when intended for nasal administration as an aqueous spray, other than by pressurized aerosol, and indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults and children between the age of 2 and 11 years of age, subject to

- a. a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and
- b. a maximum pack size of 200 doses. (S3, S4)

Nicotine, when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4mg nicotine per piece (S0), as metered sprays containing 1mg per dose or less, as nicotine transdermal patches for continuous application to the skin in strengths exceeding 21mg/24 hours, as oral solid dosage forms containing 2mg or less, or as inhalers containing 10mg or less per cartridge (S1, S3).

Omeprazole, when intended for the temporary, short-term relief of heartburn and hyperacidity, subject to:

- a. a maximum daily dose of 20 mg
- b. a maximum treatment period of 14 days. (S4)

Orlistat, when used in a dose not exceeding 60mg per main meal and not exceeding a maximum dose of 180mg per 24-hour period. (S3)

Perfluorooctane, except when intended for intraocular use. (S4)

[Proguanil when used in combination with chloroquine and intended specifically for malaria prophylaxis. (S4)]

Retapamulin, when intended for topical application to the skin, nares and external ear. (S4)

- END SCHEDULE 2

SCHEDULE 3

Colecalciferol see Vitamin D.

[Beclomethasone – see corticosteroids.]

Beclomethasone dipropionate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray; other than by pressurised aerosol, and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- (a) a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril and
- (b) a maximum pack size of 200 doses. (S2, S4)

Cyphenothrin (Pyrethroid), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Budesonide, when intended for inhalation **[and for]** or nasal administration. (S4)

Butecosone, when intended for inhalation **[and for]** or nasal administration.

[Corticosteroids (natural or synthetic), when contained in preparations intended for inhalation, except -

- a. beclomethasone dipropionate, when intended for nasal administration, other than by aerosol, indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to a maximum dose per nostril of 100 micrograms, a maximum daily dose per nostril of 200 micrograms and a pack size limited to 200 doses; and**
- b. flunisolide, when intended for nasal administration, other than by aerosol, in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to, in the case of adults and children over the age of 16 years, a maximum dose per nostril of 50 micrograms and a maximum daily dose per nostril of 100 micrograms, and in the case of children 12 to 16 years, a maximum dose per nostril of 25 micrograms and a maximum daily dose per nostril of 75 micrograms and a pack size limited to 240 doses; and**
- c. fluticasone propionate, when intended for nasal administration, other than by aerosol, in the short-term (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over 12, subject to a maximum daily dose per nostril of 100 micrograms and a pack size limited to 120 doses. (S2, S4)]**

Corticosteroids (natural or synthetic), except when listed separately in the Schedules, when contained in preparations intended for inhalation or nasal administration (S4)

[Flunisolide – see corticosteroids.]

Flunisolide, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, in a strength not exceeding 0,025 percent (m/v), and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- (a) a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms of per nostril in the case of adults and children over 16 years of age;
- (b) a maximum dose of 25 micrograms per nostril and a maximum dose of 75 micrograms in children 12 to 16 years of age
- (c) a maximum pack size of 2400 doses. (S2, S4)

[Fluticasone – see corticosteroids.]

Fluticasone propionate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the short-term (less than 6 months prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to

- (a) a maximum daily dose of 100 micrograms per nostril; and
- (b) a maximum pack size of 120 doses. (S2, S4)

[Ethambutol].

[Ethionamide].

Etofenprox (Pyrethroid), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Hydroxypropyl methylcellulose when intended for ophthalmic use (S0)

Hydrochlorothiazide.

Ibuprofen, except when used in oral medicinal preparations

- a. containing ibuprofen 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)
- b. 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, S2, S3)
- c. containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 ml in volume or in oral solid preparations in packs exceeding 24 dosage units or divided

Schedule 3

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, S2)

- d. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)
- e. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4)

Imidapril.

Indacaterol.

Influenza virus vaccine.

Lacosamide.

Macrogol (polyethylene glycol), when used for faecal impaction, or for the purposes of bowel cleansing prior to surgery or diagnostic procedures, except when intended for the treatment of constipation. (S0).

Mometasone furoate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurized aerosol, and indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults and children between the age of 2 and 11 years of age, subject to

- a. a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and
- b. a maximum pack size of 200 doses. (S2, S4)

[Nimesulide]. See inscription in S4

Nepafenac.

Nicotine, when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended), except when registered and presented as nicotine gum or lozenges (S0, S2), as metered sprays containing 1mg per dose or less (S2), as nicotine transdermal patches for continuous application to the skin (S1, S2), as oral solid dosage forms containing 2mg or less (S2) or as inhalers containing 10mg or less per cartridge (S2).

Orlistat, except when used in a dose not exceeding 60mg per main meal and not exceeding a maximum dose of 180mg per 24-hour period. (S2)

Saxagliptin.

Ticagrelor.

Schedule 3

Vitamin D (cholecalciferol) ; preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).(S0)

- END SCHEDULE 3 -

SCHEDULE 4

Algalsidase alfa.

Alglucosidase alfa.

Alginatic Acid, its salts and complexes thereof, when intended for use in gastric regurgitation, gastro-oesophageal reflux and reflux associated with hiatus hernia in infants and young children under the age of 6 years. (S0)

Altrenogest for use in animals.

Ambrisentan.

Biological medicines, injectable preparations thereof, when intended for human use and unless listed elsewhere in the Schedules,

(b) but specifically including the following

(ix) *Neisseria meningitides* [polysaccharide] vaccine

Blood collection bags, when intended for the collection and preservation of blood for subsequent use.

Beclomethasone dipropionate, except when intended for inhalation or nasal administration. (S3)

Belatacept.

Bicalutamide.

Biolimus.

Budesonide, except when intended for inhalation or nasal administration. (S3)

Cabazitaxel.

Calcium acetate, when indicated for treatment of hyperphosphataemia.

[Calcium polystyrene sulfonic acid when intended for therapeutic purposes].

Canakinumab.

Casopitant.

Chloroquine. [except when sold in combination with proguanil for malaria prophylaxis. (S2)]

Schedule 4

C[y]iclosporin.

Corifollitropin alfa.

[Corticosteroids (natural or synthetic), unless listed elsewhere in the Schedules, except –

- a. hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin; (S2)**
- b. triamcinolone when intended for application to oral lesions; (S2) and**
- c. when contained in preparations intended for inhalation. (S2, S3)]**

Corticosteroids (natural or synthetic), unless listed elsewhere in the Schedules, except –

- (a) hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin; (S2)
- (b) triamcinolone when intended for application to oral lesions; (S2) and
- (c) when contained in preparations intended for nasal administration. (S2, S3)

Daptomycin.

Deconexent (DHA) 380, when indicated for the treatment of hypertriglyceridaemia.

Deferipone.

Degarelix.

Dronedarone.

Eicosapent (EPA) 460, when indicated for the treatment of hypertriglyceridaemia.

Eltrombopag.

Eptacog alfa.

Etravirine.

Fingolimod.

Flunisolide, except when intended for inhalation or nasal administration. (S2, S3).

Fluticasone except when intended for inhalation or nasal administration. (S2, S3).

Follitropin alfa.

Gamithromycin.

Golimumab.

Ibuprofen, when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S1, S2, S3)

Idursulfase.

Indacaterol.

Ixabepilone.

Ketorolac tromethamine.

Laronidase.

Levodopa.

Levosimendan.

Linagliptin.

Liraglutide.

Luprositol, when intended for veterinary use.

Maropitant, when intended for veterinary use.

Melatonin, except when used for the treatment of desynchronization (jet-lag) in doses not exceeding 6mg daily. (S2).

Micafungin.

Mometasone furoate, except when intended for inhalation or nasal administration. (S2, S3)

Nicorandil.

Nimesulide.

Nimotuzumab.

Omeprazole, except when intended for the temporary, short-term relief of heartburn and hyperacidity, subject to:

- a. a maximum daily dose of 20 mg
- b. a maximum treatment period of 14 days. (S2)

Oxyphenbutazone, except when intended and registered for the synchronization of oestrus in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Panituzumab.

Pazopanib.

Perfluorooctane, when intended for intraocular use. (S2)

[Phenylbutazone and its derivatives, unless listed in another Schedule].

Polydimethylsiloxane see Silicone oil.

Polysterene sulfonic acid when intended for therapeutic purposes.

Plerixafor.

Prasugrel.

Proguanil. [except when used in combination with chloroquine and intended specifically for malaria prophylaxis. (S2)]

Retapamulin, except when intended for topical application to the epidermis, nares and external ear. (S2)

Schedule 4

Robenacoxib.

Romiplostim.

Silodosin.

Silicone oil (polydimethylsiloxane) when intended for intraocular use.

Sodium polystyrene sulphonic acid, when indicated for therapeutic use.

Sugammadex.

Sulphonamides except when intended for application to the eyes, nares and vagina. (S2)

Tafluprost.

Terlipressin.

Thyrotropin alfa.

Tipranavir.

Trabectedin.

Tocilizumab.

Ustekinumab.

Vernakalant.

Vorinostat.

– END SCHEDULE 4 –

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following

:

- (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and
- (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.
- (iii) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

Asenapine.

Chloroform, all substances, preparations and mixtures containing more than 20 percent of chloroform. (S1), except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use. (S0, S1)

Dapoxetine.

- END SCHEDULE 5 -

SCHEDULE 6

- a. All preparations or mixtures of such substances containing or purporting to contain substances that is chemically related and incorporates a structural fragment into its structure that is similar to the structure of a listed substance and /or exhibits pharmacodynamic properties similar to the listed substance referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):
- (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
 - (ii) the esters and ethers of such substances and of the isomers referred to in (i) as well as the isomers of such esters and ethers, where the existence of isomers of such esters or ethers is possible;
 - (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
 - (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
 - (v) all preparations and mixtures of any of the above.
 - (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

[Dextromethorphan]

Phenylbutazone and its derivatives.

- END SCHEDULE 6 -

SCHEDULE 7

- a. All preparations or mixtures of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):
- (i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
 - (ii) the esters and ethers of such substances and of the isomers referred to in (i) as well as the isomers of such esters and ethers, where the existence of isomers of such esters or ethers is possible;
 - (iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;
 - (iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;
 - (v) all preparations and mixtures of any of the above.
 - (vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

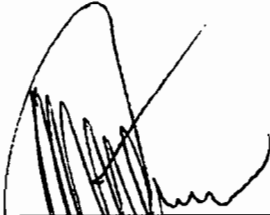
Synthetic cannabinoids (synthetic substances with cannabis-like effects), including but not limited to:

- cannabicyclohexanol;
- JWH-018;
- JWH-073;
- JWH-200;
- CP-47,497;
- CP 47,497-C6;
- CP 47,497-C7;
- CP 47,497-C8;
- CP 47,497-C9;
- HU-210

These Schedules as amended come into operation on the date of publication in the Government Gazette.

- END SCHEDULE 7 -

These Schedules as amended come into operation on the date of publication in the Government Gazette.



DR M M MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 9/3/2012
