Public Summary

Summary for ARTG Entry:	77427 UROPLEX (SANJIN TABLETS) Tablet - film coated bottle
ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	19/01/2001
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . UROPLEX (SANJIN TABLETS) Tablet - film coated bottle

Product Type Single Medicine Product **Effective Date** 14/03/2020

Permitted Indications

Traditionally used in Chinese medicine to maintain/support natural body cleansing/detoxification processes

Traditionally used in Chinese medicine to clear/dry/drain/eliminate/resolve dampness

Traditionally used in Chinese medicine to clear/expel damp-heat from the bladder

Traditionally used in Chinese medicine to helps decrease/reduce/relieve burning sensation/irritation upon urination associated with medically diagnosed cystitis

Traditionally used in Chinese medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis

Traditionally used in Chinese medicine to maintain/support urinary tract health

Traditionally used in Chinese medicine to maintain/support healthy urogenital flora

Traditionally used in Chinese medicine to maintain/support urinary tract function

Traditionally used in Chinese medicine to relieve urinary frequency

Indication Requirements

Product presentation must not imply or refer to kidney disease.

Label statement: If symptoms persist, talk to your health professional.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must only refer to medically diagnosed cystitis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Lygodium japonicum whole plant Extract dry concentrate	**52 mg**
Equivalent: Lygodium japonicum (Dry)	832 mg
Rosa laevigata root Extract dry concentrate	**92.5 mg**
Equivalent: Rosa laevigata (Dry)	1.48 g
Smilax china rhizome Extract dry concentrate	**75 mg**
Equivalent: Smilax china (Dry)	1.2 g

Other Ingredients (Excipients)

iron oxide black
iron oxide red
iron oxide yellow
lecithin
magnesium stearate
maize starch
microcrystalline cellulose
polyvinyl alcohol
purified talc
silicon dioxide
titanium dioxide
xanthan gum

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