Public Summary

Summary for ARTG Entry:	312303 Fluid Plex
ARTG entry for	Medicine Listed
Sponsor	The Pharmaceutical Plant Company Pty Ltd
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia
ARTG Start Date	7/12/2018
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

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.

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 . Fluid Plex

Product Type Single Medicine Product **Effective Date** 7/12/2018

Permitted Indications

Traditionally used in Western herbal medicine to aids/assists natural kidney cleansing/detoxification processes

Traditionally used in Western herbal medicine to enhance/promote/increase urine output

Indication Requirements

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

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

Product presentation must not imply or refer to kidney disease.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Althaea officinalis root Extract liquid	**100 microlitre/mL**
Equivalent: Althaea officinalis (Dry)	50 mg/mL

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Eupatorium purpureum root Extract liquid	**150 microlitre/mL**
Equivalent: Eupatorium purpureum (Dry)	75 mg/mL
Hydrangea arborescens root Extract liquid	**150 microlitre/mL**
Equivalent: Hydrangea arborescens (Dry)	75 mg/mL
Petroselinum crispum herb Extract liquid	**400 microlitre/mL**
Equivalent: Petroselinum crispum (Dry)	400 mg/mL

Other Ingredients (Excipients)

glycerol

Peppermint Oil

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