Australian Government

Department of Health

Therapeutic Goods Administration

# Public Summary

| **Summary for ARTG Entry:** | 189049 | Sublingual B12 1000 |
|---|---|---|
| **ARTG entry for** | Medicine Listed | |
| **Sponsor** | Herbs of Gold Pty Ltd | |
| **Postal Address** | PO Box 3143, KIRRAWEE, NSW, 2232<br>Australia | |
| **ARTG Start Date** | 9/09/2011 | |
| **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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Sublingual B12 1000

| **Product Type** | Single Medicine Product | **Effective Date** | 29/08/2019 |
|---|---|---|---|

**Permitted Indications**

Maintain/support energy production

Maintain/support general health and wellbeing

Aid/assist healthy red blood cell production

Maintain/support red blood cell health

Maintain/support blood health

Helps maintain/support haemoglobin formation/synthesis

Maintain/support cardiovascular system health

Maintain/support immune system health

Aid/assist/helps glucose/sugar/carbohydrate metabolism

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)

Maintain/support cognitive function/mental function

Maintain/support brain function

Maintain/support brain health

Maintain/support nervous system health

Maintain/support nervous system function

**Indication Requirements**

Product presentation must not imply or refer to serious cardiovascular conditions.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is

inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

| Pack Size | Poison Schedule |
|---|---|

**Components**

**1 . Formulation 1**

| | |
|---|---|
| **Dosage Form** | Tablet, orally disintegrating |
| **Route of Administration** | Oral |

**Visual Identification**

**Active Ingredients**

| | |
|---|---|
| **cyanocobalamin** | **1 mg** |

**Other Ingredients (Excipients)**

**calcium hydrogen phosphate dihydrate**
**colloidal anhydrous silica**
**magnesium stearate**
**mannitol**
**microcrystalline cellulose**
**sorbitol**