

**COMPLEMENTARY MEDICINE**  
**Western Herbal Medicine**

**SCHEDULING STATUS**

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**1. NAME OF THE MEDICINE**

**IMMUNADUE CAPSULES** (hard gelatine capsules)

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains:

<i>Hypoxis rooperi</i> T.Moore (African Wild Potato)	200 mg
<i>Sutherlandia frutescens</i> (L.) R.Br.	80 mg
<i>Uncaria tomentosa</i> (Willd. ex Schult.) DC. (Cat's claw) [root powder]	80 mg
<i>Medicago sativa</i> L. (Alfalfa) [herb top]	40 mg
<i>Hordeum vulgare</i> L. (Barley)	20 mg
<i>Aloe ferox</i> Mill. (Aloe)	10 mg
<i>Vaccinium myrtillus</i> L. (Bilberry, Fruit) *Dried Fruit Equivalent	2,2 mg*

Sugar free

For full list of excipients, see section 6.1.

**3. PHARMACEUTICAL FORM**

Hard gelatine capsules.

IMMUNADUE CAPSULES come in white gelatine capsules with "IMMUNADUE" printed in blue ink filled with a fine brown powder.

**4. CLINICAL PARTICULARS**

**4.1. Therapeutic indications**

A supplement that helps to support the immune system functions and improves general well-being.

**4.2. Posology and method of administration**

**Posology**

Adults: Take one (1) capsule Three (3) times per day.

Children older than 6 months: ½ to 1 capsule daily.

May be opened and mixed with porridge or yoghurt.

To be taken before meals with water. Take the last capsule before 5 pm OR just before bedtime.

## **Method of administration**

Take orally.

### **4.3. Contraindications**

This product should not be used by patients who have an allergy or are hypersensitive to any of the ingredients.

If symptoms worsen, consult a relevant health care provider.

### **4.4. Special warnings and precautions for use**

Do not exceed the stated recommended daily dose.

Safety in pregnancy and when breastfeeding has not been established for this multiple substance product (see section **4.6. Fertility, pregnancy and lactation**).

### **4.5. Interactions with other medicines and other forms of interaction**

#### **Interaction with Medicines**

**ANTICOAGULANT OR ANTIPLATELET MEDICINE:** Concomitant use may increase the risk of bleeding if used with anticoagulant or antiplatelet medicine.

**WARFARIN:** Alfalfa contains a large amount of vitamin K. This could theoretically interfere with the activity of warfarin. Aloe latex has stimulant laxative effects. In some people aloe latex can cause diarrhea. Diarrhea can increase the effects of warfarin, increase international normalized ratio (INR), and increase the risk of bleeding. Advise patients who take warfarin not to take excessive amounts of aloe vera.

**ANTIDIABETES MEDICINES:** Concomitant use with antidiabetic medicines might increase the risk of hypoglycemia.

**IMMUNOSUPPRESSANT MEDICINES:** Cat's claw might interfere with immunosuppressive therapy. Research shows cat's claw has been shown to have immunostimulating activity. It stimulates phagocytosis and increases respiratory cellular activity and the mobility of leukocytes. This could thus interfere with the activity of immunosuppressant medications. Alfalfa might decrease the efficacy of immunosuppressive therapy.

**DIGOXIN:** Overuse of aloe latex can increase the risk of adverse effects from cardiac glycoside drugs, such as digoxin, due to potassium depletion. Overuse of aloe, along with cardiac glycoside drugs, can increase the risk of toxicity.

#### **Interaction with Herbs and Supplements**

**ANTICOAGULANT/ANTIPLATELET HERBS AND SUPPLEMENTS:** Theoretically, cat's claw may have antiplatelet effects, thus could increase the risk of bleeding in some patients.

HERBS AND SUPPLEMENTS WITH HYPOTENSIVE EFFECTS: Cat's claw and African wild potato might have hypotensive effects, thus might increase the risk of hypotension.

#### **Interactions with Foods**

None known.

#### **Interactions with Lab Tests**

SODIUM PERTECHNETATE: The interpretation of nuclear medicine examination requiring radiobiocomplex sodium pertechnetate may be altered in patients taking cat's claw; avoid use. Animal research suggests that oral intake of cat's claw extract (*Uncaria tomentosa*) can alter the biodistribution of sodium pertechnetate.

URINE DRUG SCREENS: The barley constituent, hordenine, can yield false-positive test results with ELISA, RIA and TLC urine assays for a number of opiate drugs. Positive urine test results should be confirmed with the more sensitive GC/MS or HPLC assay.

#### **4.6. Fertility, pregnancy and lactation**

Safety in pregnancy and when breastfeeding has not been established (see section **4.4. Special warnings and precautions for use**).

The effect on fertility is unknown.

#### **4.7. Effects on ability to drive and use machines**

There is no known effect on the ability to drive and use machines.

#### **4.8. Undesirable effects**

The most common adverse effects include abdominal discomfort, cramps, diarrhoea, flatulence, anxiety, nausea, vomiting, dark-coloured stool.

Serious side effects include allergic reactions in sensitive individuals.

If adverse effects do occur, please discontinue use and consult your physician.

#### *Reporting of suspected adverse reactions:*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**" found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>.

#### **4.9. Overdose**

There is insufficient reliable information available about the presentation or treatment of overdose.

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8. Undesirable effects).

Treatment is symptomatic and supportive.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

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#### ***Hypoxis rooperi* T.Moore (African Wild Potato)**

Orally, African wild potato is used for urinary tract infections (UTIs), benign prostatic hyperplasia (BPH), prostate cancer, lung disease, diabetes, tuberculosis, chronic fatigue syndrome (CFS), osteoarthritis, psoriasis, and cancer. It is also used for maintaining health in individuals who have HIV/AIDS. African wild potato might have anti-inflammatory and free-radical scavenging activity. It seems to inhibit the production of cyclooxygenase (COX)-1 and COX-2 prostaglandin biosynthesis.

#### ***Sutherlandia frutescens* (L.) R.Br.**

*Sutherlandia frutescens* (L.) R.Br. is an indigenous medicinal plant extensively used in South Africa to treat a variety of health conditions.

The therapeutic properties of *Sutherlandia* are based on its ability to help the human body to mobilise its own immunologic and physiologic resources to help combat diseases and fight mental and emotional stress.

In vitro and in vivo studies carried out on the leaf and whole plant extracts have provided evidence of its antiproliferative, antiviral, antistress, antidiabetic, anti-inflammatory, antimutagenic, antibacterial, antioxidant, and antithrombotic properties.

The mechanism of action of *S. frutescens* for these disease and conditions is not known. Various chemical compounds that might be responsible for the activity of *Sutherlandia* have been isolated. These include triterpenoids, saponins, flavonoids, c-aminobutyric acid (GABA) and pinitol.

#### ***Uncaria tomentosa* (Willd. ex Schult.) DC. (Cat's claw)**

Cat's claw is a woody vine native to the Amazon rainforest and other tropical areas of South and Central America. Traditionally, cat's claw has been used orally and/or topically for bacterial and viral infections, as well as wound healing. According to research, the anti-inflammatory properties of *Uncaria tomentosa* may result from their ability to inhibit TNF-alpha and prostaglandin E2 (PGE2) production. The plant contains both alkaloids and flavonols which exhibits effective antioxidant and anti-inflammatory activity. According to animal research, cat's claw (*U. tomentosa*) extracts indirectly modulate immune activity and induce a higher reserve of myeloid progenitors in the bone marrow due to biologically active cytokine release (CSFs, IL-1, and IL-6).

#### ***Medicago sativa* L. (Alfalfa)**

Alfalfa is a perennial plant, of which various parts of the plant have been used in dietary supplements. Traditionally, alfalfa has been used for a variety of medical conditions, including gastrointestinal complaints, rheumatoid arthritis (RA), asthma, menstrual irregularities, and

bladder, kidney, and prostate issues. Vitamins A, C, E, and K, minerals, and trace elements are present in alfalfa. Alfalfa contains coumestrol, a phytoestrogen, and flavonoids which have high concentrations of manganese.

### ***Hordeum vulgare* L. (Barley)**

Barley is used for hypercholesterolemia, obesity, bronchitis, diarrhea, gastritis, and inflammatory bowel conditions such as ulcerative colitis. Barley is also used for preventing gastric cancer and colorectal cancer. It is also used for diabetes, hypertension, and for increasing strength and stamina. research shows that soluble fiber such as barley might increase the excretion of bile acids or neutral sterols (cholesterol precursors), increase catabolism of low-density lipoprotein (LDL) cholesterol, and reduce fat absorption. Several mechanisms have been proposed for blood pressure reduction, including an increase in electrolyte and water excretion, alteration of gastric emptying time, and an increase in fecal mineral loss.

### ***Aloe ferox* Mill. (Aloe)**

The immunostimulatory effects of aloe may play a role in its wound healing and anti-inflammatory effects. A mannose-rich polysaccharide fraction of aloe gel has been shown in mice to enhance antibody production.

### ***Vaccinium myrtillus* L. (Bilberry, Fruit)**

Bilberry contains several compounds that have demonstrated biological activity. The main chemicals contained in bilberry extract have been shown to be anthocyanidins, anthocyanins, and anthocyanosides; as well as flavonoids, quercetin, epicatechin, hydroquinone, oleanolic acid, neomyrtillin, sodium, tannins, and ursolic acid. Bilberry also contains resveratrol. The anthocyanosides, tannins, and flavonoids have been of particular scientific interest. Flavonoids have been shown in vitro to possess a number of biological properties, including inhibition of prostacyclin synthesis, reduction of capillary permeability and fragility, free radical scavenging and anti-oxidant properties, inhibition of a wide range of enzymes, impairment of coagulation and platelet aggregation, and anti-carcinogenicity.

## **5.2. Pharmacokinetic properties**

There is no clinical pharmacokinetic data available on IMMUNADUE CAPSULES to clarify the pharmacokinetic properties.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Magnesium stearate,  
colloidal silicon dioxide and  
size 0 white capsule shell.

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf life**

The shelf life for IMMUNADUE CAPSULES is 24 months.

**6.4. Special precautions for storage**

Store at or below 25 °C in an airtight container, protected from light.

KEEP OUT OF REACH OF CHILDREN.

**6.5. Nature and contents of container**

IMMUNADUE CAPSULES (100) is packed in a white plastic bottle with purple screw-on cap containing 100 capsules.

IMMUNADUE CAPSULES (50) is packed in a white plastic bottle with blue screw-on cap containing 50 capsules.

**6.6. Special precautions for disposal and other handling**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Starchoice Marketing (Pty) Ltd

429 Dekgras Street

Silvertondale

Pretoria

Tel: (012) 546 9822

**8. REGISTRATION NUMBER(S):**

To be allocated.

**9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**

To be allocated.

**10. DATE OF REVISION OF THE TEXT**

To be allocated.

**This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.**