

## Proposed Professional Information

Complementary Medicine

Discipline specific Combination product

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

## SCHEDULING STATUS

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## 1. NAME OF THE MEDICINE

SKIN + DIGESTION

### Strength

Multicomponent

### Pharmaceutical form

Film Coated Tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
Ingredients	Amount per tablet
<i>Aloe vera</i> (Aloe vera) [leaf, extract dry concentrate providing 400 mg dried herb equivalent]	2 mg
contains Hydroxyanthracene derivatives calculated as anhydrous barbaloin	400 µg
<i>Arctium lappa</i> (Burdock) [root, extract dry concentrate providing 1 g dried herb equivalent]	50 mg
<i>Calendula officinalis</i> (Marigold) [flower, extract dry concentrate providing 400 mg dried herb equivalent]	40 mg

<i>Curcuma longa</i> (Turmeric) [rhizome, extract dry concentrate providing 750 mg dried herb equivalent]	75 mg
<i>Gentiana lutea</i> (Gentian) [root, extract dry concentrate providing 75 mg dried herb equivalent]	7,5 mg
<i>Zingiber officinale</i> (Ginger) [root, extract dry concentrate providing 200 mg dried herb equivalent]	20 mg
Riboflavin sodium phosphate providing Riboflavin (Vitamin B2)	26,67 mg 20 mg
Calcium Pantothenate providing Pantothenic acid (Vitamin B5)	21,84 mg 20 mg
Pyridoxine hydrochloride providing Pyridoxine (Vitamin B6)	12,16 mg 10 mg
Ascorbic acid (Vitamin C)	50 mg
Quercetin dihydrate providing Quercetin	56 mg 50 mg
d-alpha-Tocopheryl acetate providing Vitamin E	18,38 mg 25 IU
Colloidal anhydrous silica providing Silicon (elemental)	215 mg 100 mg
Zinc citrate dihydrate providing Zinc (elemental)	46,74 mg 15 mg
Glutamine	250 mg
Lysine hydrochloride providing Lysine	187,5 mg 150 mg
Pectin (Apple Pectin)	50 mg

No added sugars.

Vegan formula. SKIN + DIGESTION does not contain crustacea, egg, fish, milk, peanut, sesame, tree nut or animal products.

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Film coated tablets

Oval, dark green, film coated tablets with a score line through the middle.

### **4. CLINICAL PARTICULARS**

#### **4.1. Therapeutic indications**

- Skin + Digestion helps to maintain and support skin health.
- Vitamin C maintains and supports connective tissue health and assists in wound healing.
- Zinc helps in connective tissue formation and maintaining healthy skin.
- Burdock is traditionally used in Western herbal medicine as a blood cleanser and to relieve minor skin eruptions.
- Turmeric is traditionally used in Western herbal medicine to relieve digestive discomfort and to promote bile secretion.
- Vitamins B5 and C, along with Zinc, assist in the metabolism of fat, protein and carbohydrates.

#### **4.2. Posology and method of administration**

##### **Posology**

Adults only, take 1 tablet with water twice per day after meals, or as directed by a health professional.

##### **Paediatric population**

Not to be used by children under 18 years of age.

##### **Method of administration**

For oral use

#### **4.3. Contraindications**

- Hypersensitivity to the active substance or to any of the excipients or residues from the manufacturing process  
This product should not be used:
  - in pregnancy or breastfeeding.
  - where abnormal constrictions of the GI tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes are present.
  - where acute stomach irritation, inflammation and stomach or duodenal ulcers are present.
  - where oedema due to impaired heart and kidney function is present.

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

- Vitamins and minerals can only be of assistance if dietary intake is inadequate.
- A health care professional should be consulted if symptoms persist.
- Contains Zinc which may be dangerous if taken in large amounts or for a long period.
- This product contains Aloe Vera.
- This product may have a laxative effect.
- Use of this product should be ceased, and a health care professional consulted, as soon as possible, if symptoms such as tingling, burning or numbness occur.  
(Contains Vitamin B6).
- Use of this product should be ceased if symptoms such as abdominal pain, cramps, spasms and /or diarrhoea occur.
- Use of this product should be ceased if a hypersensitivity reaction occurs.
- A health care professional should be consulted prior to use where the following is present:
  - diabetes
  - faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever.
  - kidney disorder.

- gallstones or a bile duct obstruction.
- where cardiac medications are being taken.
- where thiazide diuretics, corticosteroids, licorice root or other medications or health products that may aggravate electrolyte imbalance are being taken.
- A relevant health care provider should be consulted for use beyond 12 weeks (Contains Quercetin).

### **Paediatric population**

In general, health supplements should not be intended for supply to any children under the age of seven (7) months old unless where supplementation is medically warranted.

Not to be used by children under 18 years of age.

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

This product may have the potential to interact with other medicines.

### **Additional information on special populations**

Not available.

### **Paediatric population**

Not applicable as this product is not indicated for use in children,

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

This product should not be used in pregnancy and breastfeeding. (See section 4.3)

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

The effect of SKIN + DIGESTION on the ability to drive and use machines is not known.

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

##### **a. Summary of the safety profile**

The safety of SKIN + DIGESTION has not been evaluated.

Health supplements are intended only to complement health or supplement the diet and are generally regarded as safe when used as indicated. Safety data for long term use is not available.

##### **b. Possible adverse reactions**

<b>System Organ Class</b>	<b>Undesirable effect</b>	<b>Frequency</b>
Immune system disorders	Hypersensitivity reaction	Unknown

#### **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. Health care 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**

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

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic properties**

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The Pharmacological action is achieved by the combination of ingredients that helps to maintain and support skin health, maintains and supports connective tissue health and assists in wound healing, helps in connective tissue formation and maintaining health skin, acts as a blood cleanser and to relieve minor skin eruptions, relieves digestive discomfort and to promote bile secretion and assist in the metabolism of fat, protein and carbohydrates.

## **5.2. Pharmacokinetic properties**

Pharmacokinetic studies have not been conducted SKIN + DIGESTION.

## **5.3. Preclinical safety data**

No preclinical safety data available

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1. List of excipients**

Calcium hydrogen phosphate dihydrate, carnauba wax, chlorophyllin-copper complex, colloidal anhydrous silica, croscarmellose sodium, crospovidone, hypromellose, macrogol 400, macrogol 8000, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized maize starch

## **6.2. Incompatibilities**

Not applicable

## **6.3. Shelf life**

2 years

## **6.4. Special precautions for storage**

Store below 25 °C in a cool, dry place away from sunlight.

**6.5. Nature and contents of container**

Amber PET plastic bottle with a white label and a black screw cap with tamper evident band. Pack sizes: 60 tablets.

**6.6. Special precautions for disposal**

No special requirements

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

MC Pharma (Pty) Ltd

62 Constantia Avenue

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Centurion

0157

**8. REGISTRATION NUMBER**

To be allocated

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

December 2022

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