ViralChoice Zinc + C Chewable tablets - PIL Patient Information leaflet Final V7

Date: 14 April 2021

#### PATIENT INFORMATION LEAFLET

ViralChoice® Vitamin C + Zinc (chewable tablets)
Contains sugar and non-nutritive sweetener

**SCHEDULING STATUS: [S0]** 

#### **CATEGORY AND CLASS:**

Class D: Complementary Medicines:

Health supplement 34.12 Multiple substance formulation

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

#### PROPRIETARY NAME AND DOSAGE FORM:

**VIRALCHOICE® VITAMIN C + ZINC (chewable tablets)** 

#### The active substances per tablet are:

Ascorbic Acid (Vitamin C) 150.00 mg

Sodium Ascorbate (Vitamin C) 112.50 mg

Zinc Gluconate 45.00 mg

Providing Zinc 6.5 mg

Contains Sugar (Glucose

monohydrate)

370 mg

Contains sweetener (Sucralose) 4 mg

### Excipients.

Glucose monohydrate, Microcrystalline Cellulose, Sucralose, Cognis Betatene Dunaliella Salina Natural Mixed Carotenoids 1% [antioxidant] excipient), Silicon Dioxide, Trusil Natural Oranqe Flavour, Magnesium Stearate (Vegetable)

#### Read all of this leaflet carefully because it contains important information for you.

ViralChoice® Vitamin C + Zinc chewable tablets are available without a doctor's prescription for you to maintain your health. Nevertheless, you still need to take ViralChoice® Vitamin C + Zinc chewable tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ViralChoice<sup>®</sup> Vitamin C + Zinc chewable tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

Date: 14 April 2021

#### What is in this leaflet.

- 1. What ViralChoice® Vitamin C + Zinc chewable tablets are and what it is used for.
- 2. What you need to know before you take ViralChoice® Vitamin C + Zinc chewable tablets
  - a. Contra-indications
  - b. Warnings and precautions
  - c. Possible side effects.
  - d. Interactions
- 3. How to take ViralChoice® Vitamin C + Zinc chewable tablets
- 4. Possible Side effects when taking ViralChoice® Vitamin C + Zinc chewable tablets
- 5. How to store ViralChoice® Vitamin C + Zinc chewable tablets
- **6.** Description of contents of the pack and container information.

#### 1. What ViralChoice® Vitamin C + Zinc chewable tablets are and what it is used for.

**ViralChoice® Vitamin C + Zinc** chewable tablets, is a Health supplement, is formulated to support immune system function.

- Assists in reducing duration and relieves severity of common cold symptoms
- An antioxidant for the maintenance of good health
- Helps to maintain and support healthy immune system function
- Helps to maintain healthy skin
- Supports wound healing

**ViralChoice® Vitamin C + Zinc** chewable tablets are indicated for adult and children older than 1 year of age.

Not for children younger than 1 year of age

If symptoms persist, talk to your health care provider.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance.

# 2. What you need to know before you take ViralChoice® Vitamin C + Zinc chewable tablets Do not take ViralChoice® Vitamin C + Zinc chewable tablets:

If you are allergic to any of the ingredients as listed in this Patient Information Leaflet.

#### **Contra-indications**

Contra-indicated in diabetics.

Contains glucose monohydrate.

Contains sweetener:

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Warnings and precautions

**ViralChoice® Vitamin C + Zinc** chewable tablets contain Zinc, which may be dangerous when taken in large amounts for long periods of time. Not for children under 1 year of age.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

Pregnancy

Safety during pregnancy has not been established.

Breast-feeding

Safety during breast feeding has not been established.

Fertility

No information available on fertility.

#### **Driving and using machines**

No studies on the effect on the ability to drive and use machines have been performed.

#### Possible side effects

Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice Interactions.

#### Interactions

Always tell your health care provider if you are taking any other medicines.

#### 3. How to take ViralChoice® Vitamin C + Zinc chewable tablets

Do not share medicines with any other person.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

#### The recommended dose is:

Always with food or as recommended by your health care provide

Adults and children older than 14 years: Chew 1 tablet three times daily with food or as recommended by your health care provider.

Children 1 – 13 years: Chew 1 tablet once daily with food.

If symptoms persist, see your health care provider.

Not to be used in children under 1 year of age.

ViralChoice Zinc + C Chewable tablets - PIL Patient Information leaflet Final V7

Date: 14 April 2021

Vitamin and mineral supplements should not replace a balanced diet.

#### **Method of administration**

Do not swallow whole.

Chew tablet with food.

### If you take more ViralChoice® Vitamin C + Zinc chewable tablets than you should.

Do not take a double dose to make up for a forgotten dose, take your usual dose at the usual time. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

#### 4. How to store ViralChoice® Vitamin C + Zinc chewable tablets:

- Store at or below 25 °C.
- Keep in the original container
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container/label.
- Return all unused medicine to your pharmacist for safe disposal.

#### 5. What ViralChoice® Vitamin C + Zinc chewable tablets look like and contents of the pack.

**ViralChoice® Vitamin C + Zinc** chewable tablets are speckled, orange, round tablet with flat bevelled edge and break line on one side.

60 tablets inside 227 ml white HDPE bottle.

#### **Registration No:**

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

#### **Holder of Certificate of Registration**

sanofi-aventis south africa (pty) ltd.

2 Bond Street

Midrand, 1685

South Africa.

#### This leaflet was last revised in

01 April 2021

Date of revision: To be allocated by SAHPRA.

### Registration number

N/A

Date: 14 April 2021

#### PATIENT INFORMATION LEAFLET

# ViralChoice® Echinacea, Garlic, Vitamin C + Zinc (Film coated Tablet) Sugar free

#### **SCHEDULING STATUS [S0]**

#### **CATEGORY AND CLASS**

Class D: Complementary Medicines:

Discipline Specific: 33.7 Combination product

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

use.

# PROPRIETARY NAME AND DOSAGE FORM VIRALCHOICE® ECHINACEA, GARLIC, VITAMIN C + ZINC (tablets)

#### The active substances per tablet are:

Echinacea purpurea (Echinacea herb juice dry) [Fresh herb, 45:1 extract 1000 mg of fresh herb equivalent]	22.22 mg
Allium Sativum (Garlic) [Fresh bulb, 12:1 extract providing 100 mg of fresh bulb equivalent]	8.33 mg
Ascorbic acid (Vitamin C)	500.00 mg
Zinc Gluconate Providing Zinc	14.00 mg 2.00 mg

#### **Excipients:**

Calcium hydrogen phosphate dihydrate, croscarmellose sodium, crospovidone, dl-alpha-tocopherol, hypromellose, macrogol 400, magnesium stearate, maize starch, microcrystalline cellulose, povidone, silicon dioxide, vanillin.

Sugar Free.

Read all of this leaflet carefully because it contains important information for you.

ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets are available without a doctor's prescription for you to maintain your health. Nevertheless, you still need to take ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

Date: 14 April 2021

#### What is in this leaflet

- 1. What ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets is and what it is used for.
- 2. What you need to know before you take ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets
  - a. Contra-indications
  - b. Warnings and precautions
  - c. Possible side effects.
  - d. Interactions
- 3. How to take ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets
- 4. Possible Side effects when taking ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets
- 5. How to store ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets
- **6.** Description of contents of the pack and container information.

#### 1. What ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets is and what it is used for.

ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets, is a discipline specific combination medicinal product formulated to reduce the duration and severity of common cold symptoms.

- · Assists in the relief of symptoms associated with mild upper respiratory tract infections
- Assists in reducing common cold symptoms
- Support healthy immune system function
- An antioxidant for the maintenance of good health
- Assists in boosting the body's resistance to cold, flu & other infections

**ViralChoice**<sup>®</sup> **Echinacea**, **Garlic**, **Vitamin C + Zinc** tablets are indicated for adult and children older than 12 years of age.

If symptoms persist, talk to your health care provider.

# 2. What you need to know before you take ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets

Do not take ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets:

If you are allergic to any of the ingredients as listed in this Patient Information Leaflet.

#### Warnings and precautions

ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets should not replace a balanced diet.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

ViralChoice Echinacea, Garlic, Zinc + Vit C (Film coated tablets)

PIL Patient Information leaflet Final V9

Date: 14 April 2021

Pregnancy

Safety during pregnancy has not been established.

Breast-feeding

Safety during breast feeding has not been established.

**Fertility** 

No information available on fertility.

### **Driving and using machines**

No studies on the effect on the ability to drive and use machines have been performed.

#### Interactions

Always tell your health care provider if you are taking any other medicines.

#### 3. How to take ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets

Do not share medicines with any other person.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

#### The recommended dose is:

Adult and children older than 12 years of age: Take 1 tablet twice daily or as recommended by your health care provider. If symptoms persist, see your health care provider.

Vitamin and mineral supplements should not replace a balanced diet.

#### Method of administration

The tablets must be taken orally without chewing. It must be taken with enough liquid.

### If you take more ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets than you should

Do not take a double dose to make up for a forgotten dose, take your usual dose at the usual time. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### 4. Side effects

Not all side effects reported for this medicine are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice

#### 5. How to store ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets

Store at or below 25 °C

ViralChoice Echinacea, Garlic, Zinc + Vit C (Film coated tablets)

PIL Patient Information leaflet Final V9

Date: 14 April 2021

- Keep in the original container
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container/label.
- Return all unused medicine to your pharmacist for safe disposal.

# 6. What ViralChoice® Echinacea, Garlic, Vitamin C + Zinc tablets look like and contents of the pack.

**ViralChoice**<sup>®</sup> **Echinacea, Garlic, Vitamin C + Zinc** tablets are oval shaped, off white to pale yellow clear film coated tablet with brown or tan speckles.

60 tablets inside 95 ml white HDPE bottle.

#### **Registration No:**

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

### **Holder of Certificate of Registration**

sanofi-aventis south africa (pty) ltd.

2 Bond Street

Midrand, 1685

South Africa.

#### This leaflet was last revised in

01 April 2021

Date of revision: To be allocated by SAHPRA.

#### Registration number

N/A

### **Product Information Leaflet** ViralChoice® C Capsules

sanofi aventis





COMPOSITION

Active ingredient	Amount/ Capsule (3 capsules)	% RDA* in 3 capsules	Role of supplement
Echinacea Ext.	80 (240) mg	-	Herbal extract with a stimulant effect on the immune system, increasing the body's natural resistance to infections, especially colds and flu.
Phytosterols (Plant sterols & sterolins)	25 (75) mg	-	Phytosterols (plant sterols and sterolins) are vitamin-like nutrients found in fresh vegetables and fruit but that are destroyed by cooking and processing of food. They are called 'immunomodulators' as they help restore and stimulate the body's immune system?. Phytosterols also lower cholesterol levels, improve prostate problems in men and have protective anticancer effects on the colon <sup>2,3,4</sup> .
L- Arginine	10 (30) mg	-	Amino acid; enhances immune function; helps recovery from stress and trauma.
L- Methionine	33.3 (100) mg	-	Amino acid; essential for the healthy functioning of the immune system and helps rid the body of toxic substances.
Absorption Enzymes	5 (15) mg	-	Adequate digestion is vital for gastrointestinal and immune system health. Digestive enzymes may be deficient in many people, especially if the diet consists mainly of cooked or processed foods. Partially digested food accumulates in the colon, leading to various gastrointestinal problems. Digestive enzymes are important to maintain and improve digestion and for immune system health.  They also increase the absorption of vitamins and minerals.
Garlic	50 (150) mg		Increases resistance to colds and flu. Alliin and allicin in garlic have antibacterial, antifungal and antiviral activity, without affecting the body's natural flora.
Vitamin A	333 (1000) RE	100	Needed for night vision, growth of skin, bones and reproductive organs; maintains integrity of mucous membranes; even a mild deficiency of vitamin A may lead to increased susceptibility to infection.
Vitamin B6	3 (9) mg	450	Metabolism of carbohydrates, proteins and fats in the diet; plays a key role in immune system responses.
Vitamin B12	4 (12) μg	1 00	Needed for healthy blood; deficiency can result in anaemia and poor resistance to infection.
Folic acid	250 (750) μg	375	Needed for healthy blood and the formation of nerve sheaths and various proteins; deficiency reduces certain immune functions.
Vitamin C	150 (450) mg	750	Stress and infection reduce the amount of vitamin C in the body. Vitamin C is needed for many functions in the body. It may also lessen the duration and intensity of a cold or flu infection.
Vitamin D	4 (12) µg	240	Usually needed for strong bones and teeth; deficiency leads to a decreased resistance to infection.
Vitamin E	10 (30) mg	300	Antioxidant; usually needed for proper function of nerves and muscles; stimulates several components of the body's immune system.
Biotin	100 (300) µg	300	Forms part of several enzyme systems and is needed for healthy functioning of the body.
Copper	0.33 (1) mg	-	Trace element – needed in small quantities for healthy functioning of the body.
Iron	2 (6) mg	43	Needed for healthy blood, preventing anaemia and increasing the body's resistance to infection.
Selenium	5 (15) µg	-	Antioxidant and together with vitamin E increases resistance to infection.
Zinc	3 (9) mg	60	Zinc deficiency may lead to a defective immune system.

\*South African Recommended Daily Allowance (RDA) for persons 10 years and older. – No South African RDA established

Note: Water-soluble vitamins are not stored in the body. Providing more than the RDA of such vitamins has no adverse effects and may in fact be beneficial, especially in people with increased nutritional requirements such as sportsmen and sportswomen or people suffering from, or recovering from, viral infections.

ViralChoice® C does not contain tartrazine, lactose, gluten, yeast, caffeine or salt.

ViralChoice® C does not contain tartrazine, lactor ViralChoice® C USES: ViralChoice® C Capsules contain a combination of echinacea, garlic, phytosterols, vitamins, minerals, trace elements and amino acids. It is a nutrient supplement and is used when the diet alone does not include enough of these substances for optimal health.

ViralChoice® C is used during times of viral infection, in winter to reduce colds and flu infection or when recovering from illness. It helps boost the immune system, reducing the risk of invasion from viruses, bacteria and other harmful microorganisms.

The functioning of the immune system lessens with age, making older people more prone to

with age, making older people more prone to colds and flu. A strong immune system helps prevent infection or minimizes the severity of infection. ViralChoice® C should be taken at the first sign of a cold or flu. It may also be taken during winter to reduce the risk of colds or flu. Vitamins, minerals and trace elements do not take the place of a

balanced diet. Your body needs carbohydrates, proteins and fats. Vitamins, minerals and trace elements cannot work without the presence of food.

CONTRA-INDICATIONS AND WARNINGS:

- CON THA-INDICATIONS AND WARNINGS:

  Do not use this product if you are allergic to any of the ingredients.

  Speak to your doctor if you are pregnant or plan to become pregnant soon or if you are breastfeeding.

  Speak to your doctor if you have immune system problems before you take this product.

DOSAGE AND DIRECTIONS FOR USE: with meals. Adults & children over 10 years:-

Adults & children over 10 years:
Maintenance dose:

ONE capsule per day, increasing to TWO capsules per day (one morning; one evening) in people experiencing additional physical and/or mental stress.

Stop ViralChoice® C for one week after every eight weeks of continuous maintenance dosage to maximize immune boosting benefits.

Short-term immune booster: -At the first sign of a cold or flu infection:

ONE capsule THREE times a day for 10 days.
Complete the 10-day booster course and the particular with the particular day.

then continue with the maintenance dose STORAGE: Store ViralChoice® C capsules in a cool, dry

place below 25 °C. Keep the lid tightly closed when not in use. Keep all medicines out of the reach of children.

IDENTIFICATION:

Orange capsules

PRESENTATION:
Packs of 30, 60 and 120 capsules each in a white, plastic, screw-top container in a unit carton with a package insert.

product. All products in the Choice range are manufactured to the highest standards and are available in leading pharmacies throughout South Africa. Quality products in the Choice range:—

Helps to preserve and rebuild joint cartilage, as well as helping to provide relief from pain, inflammation and joint stiffness. ArthroChoice™ Powerful antioxidant and immune boosting nutrients combined to provide multiple protection for long-term health. ImmunoChoice® Complex An affordable, comprehensive multivitamin and mineral supplement with Lycopene. Multi-Vit Choice™ The ultimate calcium supplement containing vitamin D, minerals and other unique bone building nutrients. OsteoChoice® Improves sexual, mental and physical energy. PerformaChoice® Long-term immune support for cold and flu management in an effervescent dosage form. ViralChoice® Effervescent Cold and flu immune system supplement. ViralChoice® Capsules ViralChoice® Vegetabs Cold and flu immune system supplement for vegetarians. ViralChoice® Junior Syrup Cold and flu immune system supplement for children. A comprehensive, balanced fruity flavoured vitamin and mineral chewtab supplement for growing children. ViralChoice® Junior Multivitamin VitaChoice® Capsules Multinutritional supplement for people with busy stressful

NAME AND BUSINESS ADDRESS:

Your natural choice for life from WINTHROP PHARMACEUTICALS (PTY) LTD 2 Bond Street, Midrand, 1685, South Africa

Toll Free No. 0800 601 228 Facsimile: 011 256 3917 e-mail: customerservice.za@sanofi-aventis.com website: www.pharmachoice.co.za

Published February 2003

References:
1. USPDI Drug Information for the Health Care Professional; 2002.

2. Bouic PJ. The role of phytosterols and phytosterolins in immune modulation: a review of the past 10 years. Curr Opin Clin Nutr Metab Care 2001;4;(6):471-5

3. Judd JT, Baer DJ, Chen SC, Clevidence BA, Muesing RA, Kramer M, Meijer GW. Plant sterol esters lower plasma lipids and most carotenoids in mildly hypocholesterolaemic adults. Lipids 2002;37;(1):33-42

4. Pizzorno JE, Murray MT. Textbook of Natural Medicine, 2nd Ed. Churchill Livingstone. 1999.

#### **Product Information Leaflet**

## **ViralChoice® Effervescent Tablets**









#### PHARMACOLOGICAL CLASSIFICATION:

COMPOSITION:

Each ViralChoice® Effervescent tablet contains:

Active ingredient	Amount/ Tablet	SA RDA for adults*	% RDA	Safe Upper Limit	Role of supplement
Vitamin C	1000 mg	60 mg	1667	2000 mg <sup>1</sup>	Stress and infection reduce the amount of vitamin C in the body. Vitamin C is needed for many functions in the body. Vitamin C has a positive influence on the body's immune system, assisting in fighting infection. <sup>2</sup> Studies have also shown that it significantly reduces the frequency of the common cold. <sup>3</sup>
Vitamin A	700 μg (2330 IU)	1000 µg (3330 IU)	70	3000 µg	Vitamin A is important for immune function as it stimulates many of the immune processes such as the production of cytokines. It also plays a role in maintaining healthy skin and mucosal surfaces. 1,2
Vitamin B6 (Pyridoxine)	10 mg	2 mg	500	100 mg	Pyridoxine plays a key role in immune system responses and a deficiency can lead to a reduction in the quality and quantity of antibody production. <sup>2</sup>
Vitamin B12 (Cyanocobalamin)	9.6 µg	1 µg	960	N.D.	A deficiency can result in an impaired immune system and poor resistance to infection. Supplementation restores immunity. <sup>2,4</sup>
Vitamin D3 (Cholecalciferol)	10 μg (400 IU)	5 μg (200 IU)	200	50 µg	Vitamin D is an important immune system regulator and assists in mounting an immune response to infection.
Vitamin E	45 mg	10 mg	450	1000 mg	Antioxidant; usually needed for proper function of nerves and muscles; stimulates several components of the body's immune system. <sup>2</sup>
Folic Acid	400 µg	200 μg	200	1000 µg	Needed for healthy blood and the formation of nerve sheaths and various proteins; a deficiency reduces certain immune functions, including antibody production. <sup>2,6</sup>
Vitamin B2 (Riboflavin)	1.6 mg	1.6 mg	100	N.D.	Riboflavin coenzymes are essential for the conversion of folic acid, vitamin B6 and B12 to their active coenzymes. <sup>7</sup> A deficiency also leads to a reduced antibody response. <sup>2</sup>
Minerals: Zinc, iron, cop of these elements is ess					ptimum functioning of the immune system. A proper balance
Copper	0.9 mg	_	-	10 mg	Trace element – needed in small quantities for healthy functioning of the body, including activation of immune cells. <sup>4,9</sup>
Iron	5 mg	14 mg	36	45 mg	Needed for healthy blood, preventing anaemia. A deficiency causes immune dysfunction. <sup>4</sup>
Selenium	80 µg	_	1	400 µg	A deficiency results in a suppressed immune function. Selenium is important for the development and activity of white blood cells. <sup>4</sup>
Zinc	7.2 mg	15 mg	48	40 mg	Zinc deficiency may lead to a defective immune system. Zinc plays a vital role in many immune system reactions, including activity of the thymus gland. <sup>4,9</sup>
Other Nutrients	1				
Echinacea Purpurea Ext.	240 mg	_	=	_	Herbal extract with a stimulant effect on the immune system, increasing the body's natural resistance to infections, especially colds and flu. 10

\*South African Recommended Daily Allowance (RDA) for persons 10 years and older.

- No South African RDA established

Note: ViralChoice® Effervescent Tablets are free from artificial flavourants, colourants, preservatives, lactose, egg, gluten, yeast, salt, caffeine, sugar, starch and tartrazine.

No ingredient of ViralChoice® Effervescent is of animal origin.

- N.D.= Not Determined.

ViralChoice® Effervescent Tablets are not the same formulation as ViralChoice® Capsules/Vegetabs

### ViralChoice® Effervescent Tablet USES:

Each ViralChoice  $^{\circledR}$  Effervescent Tablet contains a combination of echinacea, vitamins and minerals. It is formulated for those people  $% \left\{ 1,2,\ldots,n\right\}$ preferring an effervescent dosage form for long-term immune support (in a convenient one-a-day dosage). It is a nutrient supplement and is used when the diet alone does not include enough of these substances to ensure a healthy immune system. It helps boost the immune system, reducing the risk of invasion from viruses, bacteria and other harmful microorganisms, especially during times of stress and when viruses causing colds and flu are prevalent. It is important to note that vitamins and minerals do not take the place of a balanced diet.

### CONTRA-INDICATIONS AND WARNINGS:

- Do not use this product if you are allergic to any of the ingredients. • Do not take ViralChoice® Effervescent Tablets if you suffer from
- impaired kidney function or kidney stones.1
- Speak to your doctor if you have a problem with your immune system such as multiple sclerosis, before you take this product.1
- $\bullet$  Avoid using ViralChoice  $^{\circledR}$  Effervescent Tablets if taking retinoids, as they may have additive toxic effects.1
- Atopic individuals who suffer from various allergies are more likely to have an allergic reaction to ViralChoice® Effervescent Tablets.1
- . Do not exceed the recommended dose.

### PREGNANCY AND LACTATION:

Speak to your doctor if you are pregnant or plan to become pregnant soon or if you are breastfeeding before taking this medicine.

### DOSAGE AND DIRECTIONS FOR USE:

Adults and children from 9 years of age:

PerformaChoice®

Take one tablet daily, dissolved in a half to one glass of water. Children 4 to 8 years of age:-

Take half a tablet daily, dissolved in a half to one glass of water.<sup>1</sup>

Drink ViralChoice® immediately after dissolving. Stop ViralChoice® Effervescent for one week after every eight weeks of continuous preventative use, to maximize immune boosting

henefits 10 Due to the nature of the ingredients, some cloudine

### SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

If a cold or flu occurs while taking  ${\rm Viralchoice}^{\rm \circledR}$  Effervescent, stop using the product and switch to a short-term boost dose of Viralchoice® Capsules, Vegetabs or Syrup (children). After the 10 day boost dose of the Capsules, Vegetabs or Syrup (children), you may revert back to the once a day effervescent maintenance dose High doses of vitamin C can cause diarrhoea. Other gastrointestinal side-effects may also occur with Viralchoice® Effervescent Tablets.1 Allergic reactions such as urticaria and itchy eyes have also been reported with products containing echinacea. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice

#### KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

Symptoms of overdose are usually an exacerbation of the sideeffects. Treatment is symptomatic and supportive. Consult your doctor or pharmacist.

### STORAGE:

Store Viralchoice® Effervescent Tablets in a dry and cool place below 25 °C. Keep the lid tightly closed when not in use. Keep all medicines out of the reach of children.

### **IDENTIFICATION:**

Orange, scored, round effervescent tablets

### PRESENTATION:

Packs of 10 and 30 effervescent tablets in plastic tubes in a unit carton with a package insert.

NAPPI CODE: 10's 707907-001 30's 707907-002

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any

All products in the Choice range are manufactured to the highest standards and are available in leading pharmacies throughout South Africa. Quality products in the Choice range:-

ArthroChoice™ Helps to preserve and rebuild joint cartilage, as well as helping to provide relief from pain, inflammation and joint stiffness.

ImmunoChoice® Complex Powerful antioxidant and immune boosting nutrients combine to provide multiple protection for long-

Multi-Vit Choice™ An affordable, comprehensive multivitamin and mineral supplement with Lycopene. OsteoChoice® The ultimate calcium supplement containing vitamin D, minerals and other unique bone building

Improves sexual, mental and physical energy.

ViralChoice® Effervescent Long-term immune support for cold and flu management in an effervescent dosage form. ViralChoice® Capsules Cold and flu immune system supplement.

ViralChoice® Vegetabs Cold and flu immune system supplement for vegetarians. ViralChoice® Junior Syrup Cold and flu immune system supplement for children.

A comprehensive, balanced fruity flavoured vitamin and mineral chewtab supplement for growing children. ViralChoice® Junior Multivitamin

VitaChoice® Capsules Multinutritional supplement for people with busy stressful lifestyles.





## **Product Information Leaflet**

### ViralChoice® Junior





SCHEDULING STATUS:



PROPRIETARY NAME AND DOSAGE FORM:

#### COMPOSITION:

Active ingredient	Amount/ 5 (10) (20) ml	% NRV* (4-10 years 20 ml daily dose)	Role of supplement
Echinacea	50 (100) (200) mg	-	Helps boosts the immune system, increasing the body's resistance to infections.
Green tea	2.5 (5) (10) mg	-	Green tea is a powerful antioxidant, which helps inhibit bacterial growth and infection.
Rosehip	15 (30) (60) mg	-	Rosehip is one of natures richest sources of vitamin C. Rosehip contains bioflavonoids which support the benefits of vitamin C.
Vitamin C	30 (60) (120) mg	120	Vitamin C may help lessen the duration and intensity of a cold and flu infection.
Vitamin A	667 (1334) (2668) I.U.	89	A deficiency of vitamin A may lead to an increased susceptibility to infection.
Vitamin E	3 (6) (12) I.U.	54	Antioxidant which boosts several components of the immune system.
Vitamin D	120 (240) (480) I.U.	80	A deficiency of vitamin D leads to a decreased resistance to infection.
Vitamin B <sub>6</sub>	0.75 (1.5) (3) mg	176	Needed for the metabolism of carbohydrates, fats and proteins.
Vitamin B <sub>12</sub>	1 (2) (4) µg	167	Needed for growth and reproduction.
Folic acid	75 (150) (300) µg	75	Needed for healthy blood; a deficiency reduces certain immune functions.
Biotin	30 (60) (120) µg	400	Forms part of several enzyme systems and is needed for healthy functioning of the body.
Pantothenic acid	1.5 (3) (6) mg	120	The body requires more pantothenic acid in times of stress, for example during a cold or flu infection.
Selenium	15 (30) (60) µg	109	Antioxidant, which together with vitamin E increases resistance to infection.

<sup>\*</sup> NRV - Nutrient reference values

#### PHARMACOLOGICAL CLASSIFICATION:

#### INDICATIONS:

INDICATIONS:

ViralChoice® Junior contains a combination of echinacea, green tea extract, rosehip, vitamins, minerals and trace elements. It is a nutrient supplement used when the diet alone does not include enough of these substances for optimal health. ViralChoice® Junior is used in children during times of viral infection, in winter to help reduce colds and flu infection or when recovering from illness. It helps boost the immune system, reducing the risk of invasion from viruses, bacteria and other harmful micro-organisms. The immune system in children is not fully developed making them more prone to colds, flu and other infections. A strong immune system helps system in children is not fully developed making them more prone to colds, flu and other infections. A strong immune system helps reduce the risk of infection or minimizes the severity and duration of infection. ViralChoice<sup>®</sup> Junior can also be given as a booster at the first sign of a cold or flu. It may also be taken during winter to reduce the risks of colds or flu. Vitamins, minerals and trace elements do not take the place of a balanced diet. The body needs carbohydrates, proteins and fats. Vitamins, minerals and trace elements cannot work without the presence of food.

### CONTRA-INDICATIONS AND WARNINGS:

- Do not use this product if your child is allergic to any of the ingredients.
- ViralChoice® Junior contains sorbitol.
- Speak to your doctor if your child has immune system problems before you use this product.
- Speak to your doctor if symptoms of cold or flu persist, or if you notice any unusual symptoms in your child while using this

### DOSAGE AND DIRECTIONS FOR USE:

- Maintenance dose To protect against colds, flu and other infections: Children:
- 1 3 years: ONE medicine measure (5 ml) daily.
  4 10 years: ONE medicine measure (5 ml) TWICE daily (morning

and evening).

Stop ViralChoice® Junior for one week after every eight weeks of continuous maintenance dosage to maximize immune boosting benefits.

### Short-term immune booster

## At the first sign of a cold or flu infection: Children:

1-3 years: ONE medicine measure (5 ml) TWICE daily

(morning and evening) for 10 days.
4 - 10 years: TWO medicine measures (10 ml) TWICE daily

(morning and evening) for 10 days.

Complete the 10 day booster course and then continue with the maintenance dose thereafter.

STORAGE:
Store ViralChoice® Junior in a cool, dry place below 25 °C. Keep the cap tightly closed when not in use. Protect from light. Keep all medicines out of the reach of children.

### **IDENTIFICATION:**

Orange flavour: Orange coloured syrup with orange flavour.

Apple flavour: Green coloured syrup with apple flavour.

## PRESENTATION: 200 ml liquid in a brown screw cap bottle in a unit carton together

with package insert.

### NAME AND BUSINESS ADDRESS OF THE APPLICANT: Winthrop Pharmaceuticals (Pty) Ltd 2 Bond Street,

Midrand,

Gauteng

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any

- Expert Group on Vitamins and Minerals (2002). Revised review of
- vitamin B6 www.food.gov.uk, http://www.food.gov.uk
  2. Natural medicines database (2006).
  3. Expert Group on Vitamins and Minerals (2002). Revised review of vitamin B12 www.food.gov.uk, http://www.food.gov.uk

All products in the Choice range are manufactured to the highest standards and are available in leading pharmacies throughout South Africa. Quality products in the Choice range:-

CHOICE PRODUCTS			
OMEGA PORTFOLIO			
OmegaChoice™ General	High quality omega-3 supplement to help maintain general health and well-being.		
OmegaChoice Odourless™ 1500 mg	High quality omega-3 supplement for heart, brain and joint health.		
SLEEP HEALTH			
SleepChoice™	Natural sleep aid which helps in falling asleep, staying asleep and waking up refreshed.		
IMMUNE HEALTH			
ImmunoChoice®	Powerful antioxidants and immune boosting nutrients combined to provide protection for optimal health.		
ViralChoice® Effervescent	Long-term immune support for cold and flu management in an effervescent dosage form.		
ViralChoice® Capsules	Cold and flu immune system supplement.		
ViralChoice <sup>®</sup> Vegetabs™	Cold and flu immune supplement for vegetarians.		
ViralChoice® Junior	Cold and flu immune supplement syrup for children.		
ViralChoice® Junior Multivitamin	A comprehensive, balanced fruity flavoured vitamin and mineral supplement chewtab for growing children.		
MultiVitChoice™	An affordable, comprehensive multivitamin and mineral supplement with Lycopene.		
HEART HEALTH			
Stat10Choice™	Nutritional supplement to replenish depleted Co-enzyme Q10 levels.		
HeartChoice™ Optimal	Helps to improve heart health and circulation.		
HeartChoice™ Energiser	Helps to improve heart health and overall energy.		
INTESTINAL HEALTH			
GastroChoice™ IBS	Helps in relieving symptoms of Irritable Bowel Syndrome (IBS).		
GastroChoice™	Helps in restoring the balance of natural flora in conditions such as diarrhoea, traveller's diarrhoea and antibiotic associated diarrhoea		
HydraChoice™	Aids in restoring intestinal flora and in fluid and electrolyte replacement.		
WOMAN'S HEALTH			
WomansChoice™ Cranberry Max	An extra strength cranberry juice concentrate supplement, to help maintain urinary tract health.		
WomansChoice™ Intimacy	Helps improve sexual, mental and physical energy.		
MEN'S HEALTH			
PerformaChoice®	Helps improve sexual, mental and physical energy.		
BONE AND JOINT HEALTH			
ArthroChoice™	Helps to preserve and nourish joint cartilage, as well as helping to provide relief from pain, inflammation and joint stiffness.		
ArthroChoice™ Advanced	Helps to preserve and nourish joint cartilage. Provides the optimal dose of glucosamine to assist in the management of joint pain, inflammation and stiffness.		
OsteoChoice®	The ultimate calcium supplement containing vitamin D, minerals and other unique bone building nutrients.		
ENERGY PORTFOLIO			
MultiVitChoice™	An affordable, comprehensive multivitamin and mineral supplement with Lycopene.		
VitaChoice®	Multi-nutritional supplement for people with busy, stressful lifestyles.		

Preservatives: Methyl hydroxybenzoate 0,05 % m/v, Propyl hydroxybenzoate 0,01 % m/v

#### **Product Information Leaflet**



## ViralChoice® Junior Multivitamin Chewtab







COMPOSITION:

ViralChoice® Junior Multivitamin Chewtabs contains:

Active ingredient	Amount per chewtab	% RDA* 1-3 years (1 chewtab)	% RDA* 4-12 years (2 chewtabs)	Role of supplement
Vitamin A Acetate	140 µg			Beta-carotene is converted to vitamin A when needed by the body. It is an antioxidant; needed for night vision, growth of skin, bones and reproductive organs; maintains the integrity of the mucous membranes;
Beta-Carotene	400 µg	135	154	even a mild deficiency of vitamin A may lead to increased susceptibility to infection; has a synergistic antioxidant action with vitamins C and E.
Vitamin B <sub>1</sub> (Thiamine HCl)	0,9 mg	129	150	Metabolism of carbohydrates in the diet; also needed for nerve function.
Vitamin B <sub>2</sub> (Riboflavin)	1,0 mg	125	143	Metabolism of carbohydrates, proteins and fats in the diet and the production of energy.
Vitamin B <sub>6</sub> (Pyridoxine)	1,0 mg	111	125	Metabolism of carbohydrates, proteins and fats in the diet. Important in the production of neurotransmitters.
Vitamin B <sub>12</sub> (Cyanocobalamin)	2,0 µg	100	133	Needed for healthy blood and nerve sheaths; deficiencies can result in anaemia with symptoms of tiredness and poor resistance to infection.
Vitamin C	60 mg	133	267	A water-soluble antioxidant needed for many functions in the body e.g. wound healing and a healthy immune system.
Vitamin D	8,0 µg	80	160	For strong bones and teeth; deficiency leads to decreased resistance to infection.
Vitamin E	15 mg αTE	300	428	Antioxidant; also needed for proper functioning of nerves and muscles.
Folic acid	200 µg	200	133	Needed for healthy blood and optimal functioning of the nervous system; deficiency may lead to anaemia.
Biotin	40 µg	62	67	Metabolism of fats; healthy skin and hair.
Nicotinamide	10 mg	111	125	Normal tissue metabolism; improves blood circulation.
Calcium pantothenate (equiv to pantothenic acid)	10 mg	333	400	Metabolism of carbohydrates, protein and fat. Maintenance and repair of cells and tissues.
Calcium	16 mg	2	4	Calcium is the primary mineral in the development and maintenance of healthy bones and teeth. It is also important in maintaining normal cardiovascular function.
Iron	2,3 mg	15	46	Needed for healthy blood, prevents anaemia; increases resistance to infection.
Magnesium	50 mg	33	40	Needed to break down nutrients in the diet; also needed for healthy nervous system, for bone health and to prevent muscle cramps.
Manganese	0,6 mg	40	40	Trace element – needed in small quantities for healthy functioning of the body.
Selenium	60 µg	75	60	Antioxidant effect; together with vitamin E increases resistance to infection.
Zinc	3,0 mg	30	60	Deficiency may lead to a defective immune system.

Note: Water-soluble vitamins are not stored in the body. Providing more than the RDA of such vitamins has no adverse effects and may in fact be beneficial, especially in people with increased nutritional requirements such as active children or children consuming a diet lacking in fresh fruit and vegetables.

## $\label{eq:containcaffeine} Does \ not \ contain \ caffeine, \ tartrazine, \ lactose, \ egg, \ yeast, \ salt, \ gluten \ or \ artificial \ colourants.$

ViralChoice® Junior Multivitamin USES:
ViralChoice® Junior Multivitamin Chewtabs contain a combination of vitamins, minerals and trace elements. It is a nutrient supplement used when the diet alone does not include enough of these substances for optimal health. ViralChoice® Junior Multivitamin is a comprehensive vitamin and mineral supplement especially suited for growing children and those eating a poor diet lacking in essential nutrients, as it improves the nutritional status. Vitamins, minerals and trace elements do not take the place of a balanced diet. Your body needs carbohydrates, proteins and fats. Vitamins, minerals and trace elements cannot work without the presence of food.

CONTRA-INDICATIONS AND WARNINGS:

Do not use this product if your child is allergic to any of the

### • Do not use this product if your child is allergic to any of the

- Speak to your doctor if you notice any unusual side-effects in your child while taking ViralChoice® Junior Multivitamin Chewtabs.

# DOSAGE AND DIRECTIONS FOR USE: Children aged 1- 3 years: • ONE Chewtab daily. Children aged 4-12 years: • TWO Chewtabs daily.

- STORAGE:
- Store ViralChoice® Junior Multivitamin Chewtabs in a cool, dry place below 25 °C. Keep the lid tightly closed when not in use. The tablets may change colour when exposed to heat, light and moisture.
- Keep all medicines out of the reach of children.

**IDENTIFICATION:**Three differently coloured, differently flavoured round Chewtabs **PRESENTATION:**Packs of 60 Chewtabs in a white screw-top container in a unit carton with a package insert.

NAPPI CODE 704080-001

All products in the Choice range are manufactured to the highest standards and are available in leading pharmacies throughout South Africa. Quality products in the Choice range:-

ArthroChoice™ Helps to preserve and rebuild joint cartilage, as well as helping to provide relief from pain, inflammation and joint stiffness.

Powerful antioxidant and immune boosting nutrients combine to provide multiple protection for long-term health.

Multi-Vit Choice® An affordable, comprehensive multivitamin and mineral supplement with Lycopene.

OsteoChoice® The ultimate calcium supplement containing vitamin D, minerals and other unique bone building nutrients.

PerformaChoice® Improves sexual, mental and physical energy.

ViralChoice® Effervescent Long-term Immune support for cold and flu management in an effervescent dosage form. ViralChoice® Capsules Cold and flu immune system supplement.

Cold and flu immune system supplement for vegetarians. ViralChoice® Vegetabs

ViralChoice® Junior Syrup Cold and flu immune system supplement for children. ViralChoice® Junior Multivitamin A comprehensive, balanced fruity flavoured vitamin and mineral chewtab supplement for growing children.

Multinutritional supplement for people with busy stressful lifestyles.

#### VitaChoice® Capsules NAME AND BUSINESS ADDRESS:

Your natural choice for life from WINTHROP PHARMACEUTICALS (PTY) LTD 2 Bond Street, Midrand, 1685, South Africa

Toll Free No. 0800 601 228 Facsimile: 011 256 3917 e-mail: customerservice.za@sanofi-aventis.com website: www.pharmachoice.co.za

Published March 2005

- References:1. USPDI Drug Information for the Health Care Professional; 2002.
  2. Bouic PJ. The role of phytosterols and phytosterolins in immune modulation: a review of the past 10 years. Curr Opin Clin Nutr Metab Care 2001;4;(6):471-5
  3. Judd JT, Baer DJ, Chen SC, Clevidence BA, Muesing RA, Kramer M, Meijer GW. Plant sterol esters lower plasma lipids and most carotenoids in mildly hypercholesterolaemic adults. Lipids 2002;37; (1):33-42
  4. Pizzorno JE, Murray MT. Textbook of Natural Medicine, 2nd Ed. Churchill Livingstone. 1999.
  5. Up To Date 2004. edition 12.3 Calcium supplements.