3SIXTY BIOMEDICINE **FLU ARTEM**
CAPSULES

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

FLU ARTEM CAPSULES

Each capsule contains:

Extract of Artemesia Afra (African Wormwood)	10mg
Extract of Sutherlandia Frutescens (Cancer Bush)	5mg
Cannabidiol Sativa (CBD)	10mg
Zinc	6.25mg

Contains Methylcellulose and Sucrose

D 34.13 Other.
Complementary Medicine: Health Supplement.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.
FLU ARTEM Capsules is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use **FLU ARTEM Capsules** carefully to get the best results from it.
• Keep this leaflet, you may need to read it again.
• Do not share **FLU ARTEM Capsules** with any other person.
• Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What FLU ARTEM Capsules is and what is it used for
FLU ARTEM Capsules: Assists with treatment of cold, Influenza, Cough and Fever.

2. What you need to know before you take or use FLU ARTEM Capsules
Do not take FLU ARTEM Capsules
• If you are hypersensitive (allergic) to African wormwood, Cancer bush, cannabidiol, zinc, maize starch, microcrystalline cellulose, aerosol, magnesium

stearate,limonene, soybeans, hops or to any of the other ingredients in **FLU ARTEM Capsules** (listed in section 6).
• If you are pregnant or breastfeeding your baby
• Not to be given to children.

Warnings and Precautions

- Use with caution if you have mild or severe hepatic impairment (liver disease).
- Use with caution in patients with Parkinson disease.
- Patients who have or had mood problems or depression should be monitored.
- May cause delayed reactions, sedation, and drowsiness.
- Patients with dry cough and severe kidney pathology should avoid this product
- It should not be given to children, epileptics and patients suffering from duodenal ulceration
- Avoid in pregnancy and breastfeeding
- Contains allergens: No know allergens, avoid if sensitive to Cannabidiol, Artemesia Afra, Sutherlandia Frutescens, Zinc and all the other ingredients used in this product

Children and adolescents

FLU ARTEM Capsules is not recommended for use in children under the age of 18.

Other medicines and FLU ARTEM Capsules

Always tell your healthcare provider if you are taking other medicines, including complementary or traditional medicines.
Consult your doctor if you want to take **FLU ARTEM Capsules** in combination with medicines or treatments such as:
• Pain medication, such as methadone, as it may cause additive adverse effects when used concomitantly.
• Antiepileptic or anticonvulsant medication (such as brivaracetam, eslicarbazepine, rufinamide, zonisamide, valproate, topiramate and stiripentol) since concomitant use could result in liver damage due to elevated liver enzymes

- In addition, valproate may also result in low blood platelet count.

• Birth control medication, as the concomitant use with high dosages of Cannabidiol is speculated to interfere with contraceptives.

- If a female patient on hormonal contraception experiences symptoms such as spotting, additional contraceptive methods should be employed to prevent unwanted pregnancy.

• Central nervous system depressants (zopiclone, diazepam, alprazolam, clobazam etc.) as it may increase the risk of sedation and drowsiness.

- Herbs/supplements with sedative properties, such as calamus, California poppy, catnip, hops, Jamaican dogwood, kava, L-tryptophan, melatonin, sage, St. John's wort, sassafras, skullcap, and other may theoretically also have additive sedative properties when used concomitantly with Cannabidiol.

• Immunosuppressants (such as tacrolimus and sirolimus) as concomitant use may result in elevated immunosuppressant plasma levels and consequently additive side effects.
• Kinase inhibitor, everolimus, as co-administration may cause additive adverse effects.
• Antiretroviral medication, antibiotics like erythromycin and clarithromycin, antidepressants like fluvoxamine and proton pump inhibitors (PPI's) like omeprazole, since these might increase Cannabidiol plasma concentrations leading to a greater risk of side effects. Sutherlandia Frutescens May interact with antiretroviral medication such as nevirapine and atazanavir
• Phenobarbital, phenytoin, carbamazepine, prednisone and rifampicin, as it will decrease Cannabidiol plasma concentrations, which may lower the efficacy of Cannabidiol-containing products
Administration with low-therapeutic-index prescription drugs could lead to herb-drug interaction as well as limited efficacy of such drugs
Contains GABA may enhance effects of drugs used in anxiety and stress
Thujone (commonly known as Absenthism) from excessive or prolonged ingestion of Artemisia Afra include restlessness, vomiting, vertigo, tremor, convulsions and fatty degeneration of liver.

FLU ARTEM Capsules and interaction with Diseases or Impairments

FLU ARTEM Capsules with food and drink
Take **FLU ARTEM Capsules** with or without a meal
Do not take **FLU ARTEM Capsules** with alcohol as it may increase the risk of sedation and drowsiness.

Pregnancy and breastfeeding
Not recommended for use during pregnancy and lactation.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to be pregnant, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

Driving and using machines
It is not always possible to predict to what extent of **FLU ARTEM Capsules** may interfere with the daily activities of a patient.
It is possible that **FLU ARTEM Capsules** would affect the ability to drive or operate machinery, as Cannabidiol may cause delayed reactions, drowsiness, and sedation. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which of **FLU ARTEM Capsules** affects them.

3. How to take FLU ARTEM Capsules
Always take **FLU ARTEM Capsules** exactly as described in this leaflet or as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are unsure.
Adults (18 years and over)

	Recommended Daily dose (Adults 18+)		
Variant	**Capsules**	**Mg**	
FLU ARTEM Capsules	Take 2 capsule daily	Extract of Artemesia Afra (African Wormwood) Extract of Sutherlandia Frutescens (Cancer Bush) Cannabidiol Sativa (CBD) Zinc	10mg 5mg 10mg 6.25mg

Do not drink more than 2 capsule per day without health care practitioner recommendation.

If you take more FLU ARTEM Capsules than you should
Treat symptoms and support the patient.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLU ARTEM Capsules
Always take **FLU ARTEM Capsules** as recommended on this leaflet or by the health care provider.
Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
FLU ARTEM Capsules can have side effects.
Not all side effects reported for **FLU ARTEM Capsules** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking **FLU ARTEM Capsules**, please consult your healthcare provider for advice.

Side effects associated with Cannabidiol, Artemisia Afra, Sutherlandia Frutescens:
These are very serious side effects. If you have them, you may have had serious reaction to **FLU ARTEM Capsules** You may need urgent medical attention or hospitalization.
• Liver problems which may present as skin and eyes that appear yellow (Jaundice), abdominal pain and swelling itchy skin, dark urine colour, pale stool colour, chronic fatigue, Nausea, or vomiting, diarrhoea or mild diuresis

- Prolonged use may cause loss of smell
- Frequent use may cause bad taste
- May cause drowsiness
- Frequent use may cause bad taste
- In high doses may cause cardiovascular depression
- High doses and chronic use are discouraged due to harmful effects of thujone (possible addiction and cerebral dysfunction resulting from neurotoxicity)

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.
Frequent:
• Dry mouth, diarrhoea, vomiting, decreased appetite, weight loss and abdominal pain or discomfort.

• Drowsiness, sedation, delayed reactions, lethargy, dizziness, and fatigue.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **FLU ARTEM Capsules**

5. How to store FLU ARTEM Capsules
Store in a cool, dry place at or below 25 °C.
Do not refrigerate.
Do not use after expiry date.
Protect from light.
STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information
What **FLU ARTEM Capsules** contains:
Each capsule contains

Extract of Artemesia Afra (African Wormwood)	equivalent to 10mg
Extract of Sutherlandia Frutescens (Cancer Bush)	equivalent to 5mg
Cannabidiol *Cannabis sativa* L (CBD)	equivalent to 10mg
Zinc	6.55mg
Maize starch BP/EP/USP	301.95mg
Microcrystalline Cellulose 102	40mg
Aerosol 200 Pharma	3.64mg
Magnesium Stearate	23.16mg

What FLU ARTEM Capsules looks like and contents of the pack
20 capsules in a sealed container.
FLU ARTEM Capsules is a size 00 clear methylcellulose capsule

Holder of Certificate of Registration and Manufacturer
3SIXTY**BIOMEDICINE** (PTY) LTD
23 WEST STREET, HOUGHTON
JOHHANESBURG, GAUTENG
SOUTH AFRICA
2198
Tel: +27 10 593 4630
Email:info@3sixtybiomedicine.co.za
Website: https://3sixtybiomedicine.co.za

This leaflet was last revised in
Not applicable
Registration or application number
To be allocated by SAHPRA upon registration.

3SIXTYBIOMEDICINE **FLU ARTEM**
Capsules

PROFESSIONAL INFORMATION

D 34.13 Other.
Complementary Medicine: Health Supplement.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF MEDICINE

FLU ARTEM Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Extract of Artemesia Afra (African Wormwood) equivalent to 10mg
Extract of Sutherlandia Frutescens (Cancer Bush) equivalent to 5mg
Extract of Cannabidiol *Cannabis sativa* L. (CBD) equivalent to 10mg
Zinc equivalent to 6.25mg

Contains Methylcellulose and Sucrose

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Capsule

4. CLINICAL PARTICULARS:

4.1. Therapeutic indications

FLU ARTEM Capsules Assists with treatment of cold, Influenza, Cough and Fever.

4.2. Posology and method administration

Oral administration

	Recommended Daily dose (Adults 18+)	
Variant	**Capsules**	**mg**

FLU ARTEM Capsules	Take two capsule daily	Extract of Artemesia Afra (African Wormwood) Extract of Sutherlandia Frutescens (Cancer Bush) Cannabidiol Sativa (CBD). Zinc	10mg 5mg 10mg 6.25mg

Do not exceed the recommended maximum daily dose of two capsules daily without healthcare practitioner recommendation.

FLU ARTEM Capsules are indicated for adults 18 years and older.

4.3. Contraindications

- Hypersensitivity to cannabidiol, Artemesia Afra, Sutherlandla Frutescens, Zinc or other excipients listed under section 6.1.
- Safety and efficacy in children and pregnancy has not been established (see section 4.8 d).

4.4. Special warmings and precautions for use

Special care should be with **FLU ARTEM**

If you are taking other prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- The use of Cannabidiol in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes.
- People with hepatic impairment need to consume cannabidiol and Artemisia Afra with caution.
- Patients who have or had mood problems or depression should be monitored.
- Use with caution in patients with Parkinson disease. Cannabidiol may cause psychomotor slowing, sedation and or somnolence.
- High doses and chronic use Artemisa Afra are discouraged due to harmful effects of thujone possible addiction and cerebral dysfunction resulting from neurotoxicity)
- Artemisia Afra in high doses may cause cardiovascular depression
- Artemisia should not be given to children, epileptics and patients suffering from duodenal ulceration.
- Patients with dry cough and severe kidney pathology should avoid Artemisa
- May cause drowsiness
- Frequent use of Zinc may cause bad taste
- Artemisia Afra in high doses may cause cardiovascular depression
- Artemisia in high doses and chronic use are discouraged due to harmful effects of thujone (possible addiction and cerebral dysfunction resulting from neurotoxicity)
- High doses or prolonged intake of Zinc may include anosmia (loss of smell) and copper deficiency

4.5. Interaction with other medicines and other forms of interaction

Interaction can occur, Give your healthcare provider a list of all your medicines, herbs, non-prescription drugs, or dietary supplements you use.

Analgesics: The concomitant use of methadone and Cannabidiol may increase methadone levels, which might cause additive adverse effects.

Antiepileptic/anticonvulsant medication: The concomitant use of Cannabidiol and antiepileptic/anticonvulsant medication (such as brivaracetam, eslicarbazepine, rufinamide, zonisamide, valproate, topiramate and stiripentol) could increase antiepileptic drug plasma levels and elevate liver transaminases. In addition, valproate may also result in low blood platelet count.

Birth control medication: Although speculated, it is unknown whether any clinically significant drug interactions exist between the concomitant use of Cannabidiol and hormonal contraceptives. If a female patient on hormonal contraception experiences symptoms such as spotting, additional contraceptive methods should be employed to prevent unwanted pregnancy.

Central nervous system (CNS) depressants: Concomitant use of Cannabidiol with central nervous system (CNS) depressants (for example barbiturates and benzodiazepines) may increase the risk of sedation and somnolence.
Herbs/supplements with sedative properties, such as calamus, California poppy, catnip, hops, Jamaican dogwood, kava, L-tryptophan, melatonin, sage, St. John's wort, sassafras, skullcap, and other may theoretically also have additive sedative properties when used concomitantly with Cannabidiol.
Artemisia Afra may cause a positive drug-interaction with anti-depressants
Sutherlandia Frutescens contains GABA, may enhance effects of drugs used in anxiety and stress

Immunosuppressants: Co-administration of immunosuppressants (such as tacrolimus and sirolimus) and Cannabidiol may result in elevated immunosuppressant plasma levels and consequently additive adverse effects.

Kinase inhibitors: Concomitant use of Cannabidiol and everolimus (kinase inhibitor) may increase everolimus levels which might cause additive adverse effects.

Strong inhibitors of CYP3A4 or CYP2C19: Co-administration with moderate or strong inhibitors of CYP3A4 or CYP2C19 may increase Cannabidiol plasma concentrations, which may lead to a greater risk of side effects. This includes antiretroviral medication like protease inhibitors, antibiotics like erythromycin and clarithromycin, selective serotonin reuptake inhibitors (SSRI's) like fluvoxamine and proton pump inhibitors (PPI's) like omeprazole.

Strong inducers of CYP3A4 or *CYP2C19*: Co-administration with strong inducers of CYP3A4 or CYP2C19 may decrease Cannabidiol plasma concentrations, which may lower the efficacy of Cannabidiol-containing products. This includes phenobarbital, phenytoin, carbamazepine, prednisone, and rifampicin.

Sutherlandia Frutescens administration with low-therapeutic-index prescription drugs could lead to herb-drug interaction as well as limited efficacy of such drugs

Interactions with Diseases/Impairments
Hepatic impairment: The use of Cannabidiol in patients with moderate or severe hepatic impairment may cause an increase in liver enzymes (see section 4.4). Hepatoxic effects could result from high doses of Artemisia Afra
Thujone (commonly known as Absenthism) excessive or prolonged ingestion include restlessness, vomiting, vertigo, tremor, convulsions and fatty degeneration of liver.

Parkinson disease: Cannabidiol may worsen symptoms associated with Parkinson disease.

Interactions with Foods
Fats: As Cannabidiol is highly lipophilic, it dissolves easily in the fat content of food. Thus, the concomitant consumption of Cannabidiol and high fatty food may increase the solubility, absorption, and bioavailability of Cannabidiol.
Alcohol: Do not take with alcohol as it may increase the risk of sedation and somnolence.

4.6. Fertility, pregnancy, and lactation
Safety and efficacy during pregnancy and breastfeeding has not been established.
Not recommended for use during pregnancy and lactation.
No data on the effects of Cannabidiol in human fertility are available.

4.7. Effects on ability to drive and use machines
Cannabidiol may affect the ability to drive or operate machinery, as it may cause psychomotor slowing, somnolence, and sedation. Please exercise care until you are certain that your ability to perform such activities is not affected.
At low doses, Cannabidiol does not affect the ability to drive and operate machines, in low doses Cannabidiol increases alertness.
In cases where low doses cause sedation, consumers need to be advised not to drive or operate machinery until they are able to gauge whether it adversely affect their ability.

4.8. Undesirable effects
a. Summary of safety profile
Cannabidiol, Artemisia Afra, Sutherlandia Frutescens, Zinc are generally well tolerated. Effects and toxicity are dose dependent

b. Summary of adverse reactions

Gastrointestinal disorders	
Dry mouth, Weight loss Diarrhoea Vomiting Decreased appetite Abdominal pain or discomfort.	Common Common Common Common Common Common
Nervous system disorders	
Somnolence	Common

Sedation Psychomotor slowing Lethargy Dizziness Fatigue.	Common Common Common Common Common
Investigations	
Elevated liver transaminases	Not known (cannot be estimated from the available data)

c. Description of selected adverse reactions

Cannabidiol may cause several adverse reactions, of which weight loss, diarrhoea, decreased appetite, somnolence, sedation, lethargy, fatigue, and elevated liver transaminases are Cannabidiol dose-dependent. Dizziness is mostly reported when Cannabidiol is concomitantly used with clobazam, a benzodiazepine. Elevated liver transaminases mostly appears in patients with baseline elevated liver enzymes or in patients who concomitantly consume valproate or clobazam. Discontinuation or dose adjustment of valproate or clobazam is recommended if elevated liver transaminases are detected.

- Artemisia causes Thujone (commonly known as Absenthism) due excessive or prolonged ingestion include restlessness, vomiting, vertigo, tremor, convulsions and fatty degeneration of liver. In high doses or prolonged use may cause cardiovascular depression and harmful effects of thujone (possible addiction and cerebral dysfunction resulting from neurotoxicity)
- Sutherlandia Frutescens may cause dryness of mouth, occasional mild diarrhea or mild diuresis and dizziness in cachectic patients.
- Zinc may cause bad taste and nausea. In high doses or prolonged intake may include anosmia (loss of smell) and copper deficiency

d. Paediatric Population

Cannabidiol and Artemisia Afra are not recommended for use in children younger than 18 years.

e. Other Special populations

No clinical data are available on the effects of Cannabidiol Artemisia Afra, Sutherlandia Frutescens on other special populations.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of FLU ARTEM Capsules is important. It allows continued monitoring of the benefit/risk balance of FLU ARTEM Capsules . healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications:
http://www.sahpra.org.za/Publications/Index/8

4.9. Overdosage

No known side effects were reported for overdosage of Cannabidiol Artemisia Afra, Sutherlandia Frutescens and Zinc.
In overdose, side effects can be precipitated and/or be of increased severity
In the event of overdose, treatment is symptomatic and supportive

5. PHARMACOLOGICAL PROPERTIES:

FLU ARTEM assists with treatment of cold, Influenza, Cough and Fever due to the effects of:

Cannabidiol is a phytocannabinoid obtained from *Cannabis Sativa* L.
Artemisia Afra is a herbal plant that is an indigenous member of the daisy or Asteraceae family which contains various phenolic compounds such as Borneol and other volatile oils that have ant-bacterial and anti-fungal actions. The phenolic compound that has anti-bacterial and anti-fungal activity in treating bacterial infections such as sore throats and various bronchial disease as well as viral infections such as influenza.
Sutherlandia Frutescens Sutherlandia frutescens subsp. microphylla (family: Fabaceae/Leguminosa), is used for a wide range of conditions, including cancer, viral diseases and inflammatory conditions.
Zinc supplementation is effective for the prevention of acute respiratory infections in young children and zinc lozenges may reduce the duration of the common cold in adults. zinc for the prevention or treatment of SARS-CoV-2 and other viral respiratory tract infections

D 34.13 Other
Complementary Medicine: Health Supplement

5.1 **Pharmacodynamic properties**

Mechanism of action:
Cannabidiol can interact or alter the endocannabinoid signalling pathways (via the cannabinoid receptors) and the non-endocannabinoid pathways (interactions with serotonin 5-HT1A receptors, GPR55 receptors and vanilloid-1 receptors). Cannabidiol also inhibits the degradation of the endocannabinoid, anandamide, which may contribute to its antipsychotic effects. Cannabinoids and terpenes interacts synergistically, increasing the therapeutic index of cannabinoids, a process known as the entourage effect.
Cannabidiol does not cause psychomotor or cognitive impairment or strong psychoactive effects as it has a relatively weak affinity for Cannabidiol 1 receptors, primarily located in the central nervous system, and Cannabidiol 2 found in the periphery on cells with immune function and in gastrointestinal track.
Cannabidiol has antioxidant activities that begin at the level of protein transcription by activating the redox-sensitive transcription factor referred to as the nuclear erythroid 2-related factor (Nrf2)

Artemisia Afra down regulates the Th2 pathways, coinciding with its traditional use in allergic condition. Suppresses IFN-γ production was also significantly suppressed ($P<0.001$) which causes immune defences against bacterial, viral and parasitic infections, and provide

symptomatic relief by decreasing fever as it also significantly decreased IL-6 release (P <0.001).
The eucolyptol reduces severity of asthma, sinusitis and chronic obstructive pulmonary disorder (COPD). Chrysanthenyl acetate is a sesquiterpene lactone found in Artemisia with anti-inflammatory, anti-microbial and cytotoxic properties.
The volatile oils are responsible for the ant-microbial and anti-oxidant activity associated with the plant.
Artemisa Afra might contain 'pro-drugs', molecules that only become active after administration and metabolism.
Sutherlandia Frutescens Little scientific data has been documented on the mechanism by which Sutherlandia frutescens acts on the immune system. Sutherlandia frutescens extract possesses superoxide as well as hydrogen peroxide scavenging activities at concentrations as low as 10 g/ml, which could account for some of the anti-inflammatory properties that have been described. The antioxidant activity of the extract under study could possibly be related to phenolic compounds, such as tannins and flavonoids. Canavanine has also been reported to be a potent anticancer agent,28,29 as well as having antiviral activity against influenza and retroviruses. Sutherlandia extracts have anti-inflammatory, analgesic and antibacterial activity
Zinc The antiviral effects of zinc are also hypothesised to potentiate the therapeutic effects of chloroquine [44], as chloroquine acts as a zinc ionophore increasing Zn2+ influx into the cell [40]. Zinc may also modify the host's response to an infection as it is an essential co-factor element with a broad range of functions in the body. Zinc, which can inhibit rhinovirus replication and has activity against other respiratory viruses such as respiratory syncytial virus,8 is a potential treatment for the common cold. Zinc may also reduce the severity of cold symptoms by acting as an astringent on the trigeminal nerve.

Sesquiterpene lactone found in A Afra is responsible for cytotoxicity

Pharmacodynamic effects:

Cannabis Sativa L. Cannabidiol: Results from pre-clinical studies suggest Cannabidiol has anti-inflammatory, analgesic, antiemetic, antipsychotic, anti-ischemic, anxiolytic, and antiepileptiform, antioxidation and antiseizure effects

Artemisia Afra Results from pre-clinical studies suggest Artemisia Afra has effects in various disorders including coughs, colds, influenza as a traditional herbal plant African wormwood" and in Afrikaans "Wilde als". It is usually employed for treating a variety of ailments such as coughs, colds, headaches, chills, dyspepsia, loss of appetite, gastric derangements, colic, croup, whooping-cough, gout, asthma, malaria, diabetes, bladder and kidney disorders, influenza, convulsions, fever, heart inflammation, rheumatism Sutherlandia Frutescens Results from pre-clinical studies suggests Sutherlandia Frutescens has diverse medicinal uses, such as the treatment of patients suffering from internal cancers, inflammation and viral diseases. Sutherlandia is used to wash wounds and to bring down fevers. Sutherlandia frutescens is an important traditional medicine in southern Africa that has been used by various cultural groups for a very wide range of indications. Early records are rare, but suggest that the Khoi-San and early Cape settlers used Sutherlandia as a general medicine and tonic against stomach ailments and internal cancers and as a topical application for treating wounds and eye infections

Zinc has the potential to reduce inflammation, improve mucocillary clearance, prevent of ventilator-induced lung injury, and modulate antiviral immunity. Zinc supplementation shorten the duration of ARI symptoms.

5.2 Pharmacokinetic properties

Absorption: Oral bioavailability of Cannabidiol is typically very low (13 % - 19 %). This can be ascribed to first pass metabolism.
Artemisia Afra data in human not available
Sutherlandia Frutescens data in human not available
Zinc oral zinc formulations may shorten the duration of symptoms of the common cold.
The **FLU ARTEM Capsules** are prepared using a proprietary **Polimeric®** Nano-formulation which ensures 100% bioavailability.

Distribution: Cannabidiol is rapidly distributed into the tissues (volume of distribution: approximately 32 L/kg). Due to the high lipophilicity of Cannabidiol , it may preferentially accumulate in the adipose tissue. Cannabidiol and its metabolites are more than 94 % protein bound. The distribution of terpenes are unknown.
Artemisia Afra and Sutherlandia Frutescens, Zinc.

Biotransformation: Cannabidiol is vastly metabolized in the liver. It undergoes hydroxylation, oxidation, beta-oxidation, conjugation, and epoxidation. Terpenes are metabolized through cytochrome P450.
Artemisia Afra, Sutherlandia Frutescens, Zinc.

Elimination: The half-life of Cannabidiol is between 56 to 61 hours. Cannabidiol is excreted in the faeces, with minor renal clearance.
Artemisia Afra, Sutherlandia Frutescens, Zinc.

5.3 Preclinical safety data

When used orally and appropriately in adults, Cannabidiol, Artemisia Afra, Sutherlandia Frutescens and Zinc recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Maize starch BP/EP/USP	301.95mg
Microcrystalline Cellulose 102	40mg
Aerosol 200 Pharma	3.64mg
Magnesium Stearate	23.16mg

6.2 Incompatibilities

In the absence of compatibility studies, **FLU ARTEM Capsules** must not be mixed with other medicines.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store in a cool, dry place at or below 25 °C.
Do not refrigerate.
Do not use after expiry date.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents
20 capsules in a sealed container
FLU ARTEM capsule is a size 00 clear methylcellulose capsule

6.6 Special precautions for disposal
N/A

7. HOLDER OF CERTIFICATE OF REGISTRATION:
3SIXTY**BIOMEDICINE** (PTY) LTD
23 WEST STREET, HOUGHTON
JOHHANESBURG, GAUTENG
SOUTH AFRICA
2198

Tel: +27 10 593 4630
Email: info@3sixtybiomedicine.co.za
Website: https://3sixtybiomedicine.co.za

8. REGISTRATION NUMBER(S):
To be allocated by SAHPRA upon registration

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:
Not Applicable

10. DATE OF REVISION OF THE TEXT:
Not Applicable