



PRACTITIONER INFORMATION

Nature's Ultra Calm CBD Roll-on

Nature's Ultra Muscle Rub CBD

Category D: Complementary Medicine Discipline 34.13: Health Supplements. Other.

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

SCHEDULING STATUS:
Not Scheduled

1. NAME OF THE MEDICINE:

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml
Nature's Ultra Calm CBD Roll-on 600 mg 10 ml
Nature's Ultra Muscle Rub CBD 300 mg 50 g
Nature's Ultra Muscle Rub CBD 600 mg 50 g

1.1 Strength:

Nature's Ultra CBD Each 1 mL or 1 g contains:

	Nature's Ultra Calm CBD Roll-on 300 mg 10 ml	Nature's Ultra Calm CBD Roll-on 600 mg 10 ml	Nature's Ultra Muscle Rub CBD 300 mg 50 g	Nature's Ultra Muscle Rub CBD 600 mg 50 g
Active ingredients: Cannabis sativa L. cannabidiol (CBD isolate)	10.00 mg	20.00 mg	10.00 mg	20.00 mg
Other ingredients	Prunus armeniaca (Apricot) kernel oil, Argania spinosa (Argan) kernel oil, Persea gratissima (Avocado) oil, Camellia sinensis (Camellia) leaf oil, Oenothera biennis (Evening primrose) oil, Cannabis sativa (Hemp) seed oil, Melia azadirachta (Neem) seed oil, Rosa canina (Rosehip) seed oil, Prunus amygdalus dulcis (Sweet almond) oil, Lavandula angustifolia (Lavender) oil, Vetiveria zizanioides (Vetiver) root oil, Eucalyptus globulus leaf oil, Boswellia carterii (Frankincense) oil, Citrus aurantium dulcis (orange) peel oil, Cananga odorata (Ylang ylang) flower oil		Camellia sinensis (Camellia) leaf oil, Beeswax, Butyrospermum parkii (shea butter), Carthamus tinctorius (Safflower) seed oil, Menthol, Squalane, Simmondsia chinensis (Jojoba) seed oil, Cinnamomum camphora (Camphor) leaf oil, Melaleuca alternifolia (Tea tree) leaf oil, Citrus limon (Lemon) peel oil, Mentha piperita (Peppermint) oil, Eugenia caryophyllus (Clove) bud oil, Tocopheryl (Vitamin E), Arnica montana extract, Artemisia annua leaf/stem extract, Gaultheria procumbens (Wintergreen) leaf oil, Helichrysum italicum (Helichrysum) flower oil	

1.2 Pharmaceutical form:

Roll-on (10 ml)
Topical (50 g)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 1 ml dose

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml contains 10 mg Cannabidiol isolate.
Nature's Ultra Calm CBD Roll-on 600 mg 10 ml contains 20 mg Cannabidiol isolate.
Nature's Ultra Muscle Rub CBD 300 mg 50 g contains 10 mg Cannabidiol isolate.
Nature's Ultra Muscle Rub CBD 600 mg 50 g contains 20 mg Cannabidiol isolate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml is a roll-on liquid.
Nature's Ultra Calm CBD Roll-on 600 mg 10 ml is a roll-on liquid.
Nature's Ultra Muscle Rub CBD 300 mg 50 g is a topical rub.
Nature's Ultra Muscle Rub CBD 600 mg 50 g is a topical rub.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD may assist with the relief of pain and inflammation, stress, anxiety and sleeplessness related conditions.

4.2 Posology and method of administration

4.2.1 Posology

Do not exceed the recommended daily dose of 20 mg/day.

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml apply externally when necessary.
Nature's Ultra Calm CBD Roll-on 600 mg 10 ml apply externally when necessary.
Nature's Ultra Muscle Rub CBD 300 mg 50 g apply externally when necessary. Do not apply to broken skin. Massage well.
Nature's Ultra Muscle Rub CBD 600 mg 50 g apply externally when necessary. Do not apply to broken skin. Massage well.

The safety and efficacy of Nature's Ultra CBD in children has not yet been established.

4.2.2 Method of administration

Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD is for external use only. Keep away from eyes and mucous membranes.

4.3 Contraindications

Hypersensitivity to any of the ingredients (active substances or the excipients listed in 6.1). Not recommended during pregnancy or lactation, as no studies have been conducted. Not to be used in with other central nervous system depressants. Not intended for children under the age of 6 without advice of a health care professional. Not for use with infants.

4.4 Special warnings and precautions for use

There are no known warnings or special precautions for taking this medicine but it is advised to please consult your healthcare practitioner before taking this medicine.

4.5 Interaction with other medicines and other forms of interaction

Interactions with medicines

It is advised to be cautious when taking Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD with medication that has a sedative or drowsy property as it may cause increased sedation.

4.6 Fertility, pregnancy and lactation

Fertility, Pregnancy and lactation

Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD is not recommended for use during pregnancy or whilst breastfeeding, as the safety and efficacy of has not been established for this population group. Please consult your healthcare practitioner before taking this or any other supplement.

4.7 Effects on ability to drive and use machines

Cannabidiol has been demonstrated to have sedative effects. It is therefore not recommended to use Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD before using machinery, driving or other activity that requires concentration and focus.

4.8 Undesirable effects

4.8.a Summary of the safety profile

CBD seems to be well-tolerated topically.

4.8.b Summary of adverse reactions

No adverse effects have been noted or become known with the simultaneous application of CBD and other medication or food.

4.8.c Description of selected adverse reactions

CBD may cause dry mouth, diarrhoea, vomiting, decreased appetite, nausea, constipation, abdominal pain or discomfort, dyspepsia, distention and gastroesophageal reflux.

CBD may also cause lethargy, dizziness, sedation, fatigue, headache, and insomnia.

Skin and subcutaneous tissue disorders may occur in the form of Allergic dermatitis.

Treatment of over-dosage is symptomatic and supportive.

4.8.d Paediatric Population

Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD is not intended for use in children under the age of 6 without advice of a health care professional. Not for use in infants. Please consult your healthcare practitioner for advice before taking this medicine.

4.8.e Other special populations

No clinical data are available on the effects of Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD on other special populations.

4.8.f Overdose

No known side effects have been reported for over-dosage of CBD.

Treatment of over-dosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Mechanism of action:

Cannabidiol (CBD) is a cannabinoid. CBD has been shown to interact or interfere with the endocannabinoid and non-endocannabinoid signalling systems within the body.

Unlike Tetrahydrocannabinol (THC), CBD does not cause euphoria or intoxication.

Results from pre-clinical studies suggest CBD has anti-inflammatory, analgesic, anti-emetic, anti-psychotic, anti-ischemic, anxiolytic, and anti-epileptiform effects.

5.2 Pharmacokinetic properties

Cannabidiol (CBD) is a cannabinoid and is the active ingredient in this formulation which is well known. Topical CBD use is well tolerated. CBD is primarily excreted in the faeces, with minimal renal elimination.

Pharmacokinetic studies have not been performed on Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD.

5.3 Preclinical safety data

CBD has been found to have relatively low toxicity.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml and Nature's Ultra Calm CBD Roll-on 600 mg 10 ml:

- Prunus armeniaca (Apricot) kernel oil, Argania spinosa (Argan) kernel oil, Persea gratissima (Avocado) oil, Camellia sinensis (Camellia) leaf oil, Oenothera biennis (Evening primrose) oil, Cannabis sativa (Hemp) seed oil, Melia azadirachta (Neem) seed oil, Rosa canina (Rosehip) seed oil, Prunus amygdalus dulcis (Sweet almond) oil, Lavandula angustifolia (Lavender) oil, Vetiveria zizanioides (Vetiver) root oil, Eucalyptus globulus leaf oil, Boswellia carterii (Frankincense) oil, Citrus aurantium dulcis (orange) peel oil, Cananga odorata (Ylang ylang) flower oil.

Nature's Ultra Muscle Rub CBD 300 mg 50 g and Nature's Ultra Muscle Rub CBD 600 mg 50 g:

- Camellia sinensis (Camellia) leaf oil, Beeswax, Butyrospermum parkii (shea butter), Carthamus tinctorius (Safflower) seed oil, Menthol, Squalane, Simmondsia chinensis (Jojoba) seed oil, Cinnamomum camphora (Camphor) leaf oil, Melaleuca alternifolia (Tea tree) leaf oil, Citrus limon (Lemon) peel oil, Mentha piperita (Peppermint) oil, Eugenia caryophyllus (Clove) bud oil, Tocopheryl (Vitamin E), Arnica montana extract, Artemisia annua leaf/stem extract, Gaultheria procumbens (Wintergreen) leaf oil, Helichrysum italicum (Helichrysum) flower oil.

6.2 Incompatibilities

Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD 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 below 25°C.

Do not refrigerate.

Do not use after expiry date.

Keep the container tightly closed.

Protect from light and store upright.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml and Nature's Ultra Calm CBD Roll-on 600 mg 10 ml:

The product is a translucent yellow liquid with a distinct aroma, packed in a black glass bottle with a black bottle and screw on lid.

Nature's Ultra Muscle Rub CBD 300 mg 50 g and Nature's Ultra Muscle Rub CBD 600 mg 50 g: The product is an off-white to green rub with a distinct aroma, packed in a black glass bottle with a black screw cap and shive.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Young Living South Africa (Pty) Ltd
Clearwater Office Park, Building 6
Cnr of Christian de Wet and Mellenium Road
Strubensvalley, Roodepoort, Gauteng, 1724
https://www.youngliving.com/en_ZA

8. REGISTRATION NUMBER(S)

To be allocated.

Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

March 2020.

10. DATE OF REVISION OF THE TEXT

TBC

PATIENT INFORMATION LEAFLET

This leaflet tells you about **Nature's Ultra Calm CBD Roll-on** and **Nature's Ultra Muscle Rub CBD**

Complementary Medicines. Health Supplement.

Scheduling Status: Not Scheduled

PROPRIETARY NAME AND DOSAGE FORM:

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml
Nature's Ultra Calm CBD Roll-on 600 mg 10 ml
Nature's Ultra Muscle Rub CBD 300 mg 50 g
Nature's Ultra Muscle Rub CBD 600 mg 50 g

Health Supplement:

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

Please Read all of this leaflet carefully because it contains important information for you. **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** is available without a doctor's prescription.

Nevertheless, you still need to use **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Do not share **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** with any other person.

Ask your pharmacist if you need more information or advice.

You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

1. What **Nature's Ultra Calm CBD Roll-on** and **Nature's Ultra Muscle Rub CBD** is and what it is used for.
2. What you need to know before you use **Nature's Ultra Calm CBD Roll-on** and **Nature's Ultra Muscle Rub CBD**.
3. How to use **Nature's Ultra Calm CBD Roll-on** and **Nature's Ultra Muscle Rub CBD**.
4. Possible side effects.
5. How to store **Nature's Ultra Calm CBD Roll-on** and **Nature's Ultra Muscle Rub CBD**.
6. Contents of the pack and other information.

1. What Nature's Ultra CBD is used for:

Nature's Ultra Calm CBD Roll-on and **Nature's Ultra Muscle Rub CBD** may assist with the relief of pain and inflammation, stress, anxiety and sleeplessness related conditions.

2. What you need to know before you use Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD:

Do not use Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD:

- If you are hypersensitive (allergic) to CBD or any of the ingredients of **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** (listed in section 6).
- If you are taking antidepressants or sleeping tablets.

Other medicines and Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional or herbal medicines.)

Do not use **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** if you are taking antidepressant or anti-epileptic medication, as side effects of these medicines may be intensified.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your healthcare practitioner for advice before taking this medicine.

Driving and using machines:

Do not use **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** if you are driving or operating heavy machinery as **CBD** may cause drowsiness and sedation.

3. How to use Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD:

Do not share medicines prescribed for you with any other person.

Always use **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** exactly as described in this leaflet or as advised by your healthcare practitioner. Do not exceed the recommended daily dose of 20 mg/day.

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml apply externally when necessary.

Nature's Ultra Calm CBD Roll-on 600 mg 10 ml apply externally when necessary.

Nature's Ultra Muscle Rub CBD 300 mg 50 g apply externally when necessary. Do not apply to broken skin. Massage well.

Nature's Ultra Muscle Rub CBD 600 mg 50 g apply externally when necessary. Do not apply to broken skin. Massage well.

The safety and efficacy of **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** in children has not yet been established.

If you use more Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD than you should:

There are no known cases of overdose with CBD.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use your Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD:

Use your next dose at your regular time. Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects:

Nature's Ultra Calm CBD Roll-on and **Nature's Ultra Muscle Rub CBD** can have side effects.

Not all side effects reported for **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **Nature's Ultra Calm CBD Roll-on** or **Nature's Ultra Muscle Rub CBD**, please consult your healthcare practitioner for advice.

Nature's Ultra Calm CBD Roll-on or **Nature's Ultra Muscle Rub CBD** can cause drowsiness, fatigue and sedation. This is worse when used at the same time as medicines with sedative properties, including herbal or traditional medicines.

Nature's Ultra Calm CBD Roll-on or **Nature's Ultra Muscle Rub CBD** can also cause a dry mouth, diarrhoea, weight loss, nausea, constipation and vomiting with high doses.

Reporting of side effects

If you get side effects, talk to your healthcare practitioner. 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 **Nature's Ultra Calm CBD Roll-on** and **Nature's Ultra Muscle Rub CBD**.

5. How to store Nature's Ultra Calm CBD Roll-on or Nature's Ultra Muscle Rub CBD:

Store in a cool, dry place at or below 25 °C. Store upright. Do not refrigerate. Keep out of reach of children. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD contains:

The active ingredient is cannabidiol (CBD).

The other (inactive) ingredients are:

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml and Nature's Ultra Calm CBD Roll-on 600 mg 10 ml:

- Prunus armeniaca (Apricot) kernel oil, Argania spinosa (Argan) kernel oil, Persea gratissima (Avocado) oil, Camellia sinensis (Camellia) leaf oil, Oenothera biennis (Evening primrose) oil, Cannabis sativa (Hemp) seed oil, Melia azadirachta (Neem) seed oil, Rosa canina (Rosehip) seed oil, Prunus amygdalus dulcis (Sweet almond) oil, Lavandula angustifolia (Lavender) oil, Vetiveria zizanioides (Vetiver) root oil, Eucalyptus globulus leaf oil, Boswellia carterii (Frankincense) oil, Citrus aurantium dulcis (orange) peel oil, Cananga odorata (Ylang ylang) flower oil.

Nature's Ultra Muscle Rub CBD 300 mg 50 g and Nature's Ultra Muscle Rub CBD 600 mg 50 g:

- Camellia sinensis (Camellia) leaf oil, Beeswax, Butyrospermum parkii (shea butter), Carthamus tinctorius (Safflower) seed oil, Menthol, Squalane, Simmondsia chinensis (Jojoba) seed oil, Cinnamomum camphora (Camphor) leaf oil, Melaleuca alternifolia (Tea tree) leaf oil, Citrus limon (Lemon) peel oil, Mentha piperita (Peppermint) oil, Eugenia caryophyllus (Clove) bud oil, Tocopheryl (Vitamin E), Arnica montana extract, Artemisia annua leaf/stem extract, Gautheria procumbens (Wintergreen) leaf oil, Helichrysum italicum (Helichrysum) flower oil.

What Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD looks like and contents of the pack:

Nature's Ultra Calm CBD Roll-on 300 mg 10 ml and Nature's Ultra Calm CBD Roll-on 600 mg 10 ml: The product is a translucent yellow liquid with a distinct aroma, packed in a black glass bottle with a black bottle and screw on lid.

Nature's Ultra Muscle Rub CBD 300 mg 50 g and Nature's Ultra Muscle Rub CBD 600 mg 50 g: The product is an off-white to green rub with a distinct aroma, packed in a black glass bottle with a black screw cap and shive.

Holder of the certificate of registration:

Young Living South Africa (Pty) Ltd
 Cleanwater Office Park, Building 6
 Cnr of Christian de Wet and Mellenium Road
 Strubensvalley, Rodepoort, Gauteng, 1724
https://www.youngliving.com/en_ZA

This leaflet was last revised in:

March 2020.

Registration number:

TBC

Nature's Ultra Calm CBD Roll-on and Nature's Ultra Muscle Rub CBD is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use.



PRACTITIONER INFORMATION

Nature's Ultra CBD Oil Drops

Category D: Complementary Medicine Discipline 34.13: Health Supplements. Other.

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

SCHEDULING STATUS:
Not Scheduled

1. NAME OF THE MEDICINE:

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml
Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml
Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml

1.1 Strength:

Nature's Ultra CBD Each 1 mL contains:

	Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml	Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml	Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml
Active ingredients: Cannabis sativa L, cannabidiol (CBD isolate)	16.66 mg	16.66 mg	16.66 mg
Inactive ingredients	Cocos nucifera (Coconut) oil, Citrus paradise (Grapefruit) peel oil, Citrus aurantium dulcis (Orange) peel oil, Organic Stevia rebaudiana (Stevia) leaf extract.	Cocos nucifera (Coconut) oil, Mentha piperita (Peppermint) oil, Metha spicata (Spearmint) leaf extract, Organic Stevia rebaudiana (Stevia) leaf extract.	Cocos nucifera (Coconut) oil, Cinnamomum zeulanicum (Cinnamon) bark oil, Organic Stevia rebaudiana (Stevia) leaf extract.

1.2 Pharmaceutical form:
Drops (30 ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 1 ml dose

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml contains 16.66 mg Cannabidiol isolate.
Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml contains 16.66 mg Cannabidiol isolate.
Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml contains 16.66 mg Cannabidiol isolate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Transparent clear oil with earthy aroma and:

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml – Citrus flavour,
Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml – Mint flavour,
Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml – Cinnamon flavour.

4. CLINICAL PARTICULARS:

4.1 Therapeutic Indications

Nature's Ultra CBD may assist with the relief of pain and inflammation, stress, anxiety and sleeplessness related conditions.

4.2 Posology and method of administration

4.2.1 Posology

Do not exceed the recommended daily dose.

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml Take 1,0 ml orally once daily when necessary.

Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml Take 1,0 ml orally once daily when necessary.

Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml Take 1,0 ml orally once daily when necessary.

The safety and efficacy of Nature's Ultra CBD in children has not yet been established.

4.2.2 Method of administration

Take Nature's Ultra CBD Drops orally. The drops may be taken as is under the tongue or mixed with other liquids (water or juice).

4.3 Contraindications

Hypersensitivity to any of the ingredients (active substances or the excipients listed in 6.1). Not recommended during pregnancy or lactation, as no studies have been conducted. Not to be taken with other central nervous system depressants. Not to be given to children.

4.4 Special warnings and precautions for use

There are no known warnings or special precautions for taking this medicine but it is advised to please consult your healthcare practitioner before taking this medicine.

4.5 Interaction with other medicines and other forms of interaction

Interactions with medicines

It is advised to be cautious when taking Nature's Ultra CBD Drops with medication that has a sedative or drowsy property as it may cause increased sedation. Taking Nature's Ultra CBD Drops with a high-fat meal increases CBD levels in the blood compared with taking this on an empty stomach.

4.6 Fertility, pregnancy and lactation

Fertility, Pregnancy and lactation

Nature's Ultra CBD Drops is not recommended for use during pregnancy or whilst breastfeeding, as the safety and efficacy of has not been established for this population group. Please consult your healthcare practitioner before taking this or any other supplement.

4.7 Effects on ability to drive and use machines

Cannabidiol has been demonstrated to have sedative effects. It is therefore not recommended to take Nature's Ultra CBD before using machinery, driving or other activity that requires concentration and focus.

4.8 Undesirable effects

4.8.a Summary of the safety profile

CBD seems to be well-tolerated orally.

4.8.b Summary of adverse reactions

No adverse effects have been noted or become known with the simultaneous ingestion of CBD and other medication or food.

4.8.c Description of selected adverse reactions

CBD may cause dry mouth, diarrhoea, vomiting, decreased appetite, nausea, constipation, abdominal pain or discomfort, dyspepsia, distention and gastroesophageal reflux.

CBD may also cause lethargy, dizziness, sedation, fatigue, headache, and insomnia.

Skin and subcutaneous tissue disorders may occur in the form of Allergic dermatitis.

Treatment of over-dosage is symptomatic and supportive.

4.8.d Paediatric Population

Nature's Ultra CBD Drops is not recommended for use in children. Please consult your healthcare practitioner for advice before taking this medicine.

4.8.e Other special populations

No clinical data are available on the effects of Nature's Ultra CBD on other special populations.

4.8.f Overdose

No known side effects have been reported for over-dosage of CBD.

Treatment of over-dosage is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Mechanism of action:

Cannabidiol (CBD) is a cannabinoid. CBD has been shown to interact or interfere with the endocannabinoid and non-endocannabinoid signalling systems within the body. Unlike Tetrahydrocannabinol (THC), CBD does not cause euphoria or intoxication. Results from pre-clinical studies suggest CBD has anti-inflammatory, analgesic, anti-emetic, anti-psychotic, anti-ischemic, anxiolytic, and anti-epileptiform effects.

5.2 Pharmacokinetic properties

Cannabidiol (CBD) is a cannabinoid and is the active ingredient in this formulation which is well known. CBD taken by an oral route takes between 3 and 5 hours to reach maximal concentration in the blood. Oral CBD bioavailability is noted at between 13% to 19% with a half-life between 56 to 60 hours. CBD is primarily excreted in the faeces, with minimal renal elimination. Pharmacokinetic studies have not been performed on Nature's Ultra CBD Drops.

5.3 Preclinical safety data

CBD has been found to have relatively low toxicity.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml:

- Cocos nucifera (Coconut) oil, Citrus paradise (Grapefruit) peel oil, Citrus aurantium dulcis (Orange) peel oil, Organic Stevia rebaudiana (Stevia) leaf extract.

Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml

- Cocos nucifera (Coconut) oil, Mentha piperita (Peppermint) oil, Metha spicata (Spearmint) leaf extract, Organic Stevia rebaudiana (Stevia) leaf extract.

Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml

- Cocos nucifera (Coconut) oil, Cinnamomum zeulanicum (Cinnamon) bark oil, Organic Stevia rebaudiana (Stevia) leaf extract.

6.2 Incompatibilities

Nature's Ultra CBD 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 below 25°C.

Do not refrigerate.

Do not use after expiry date.

Keep the container tightly closed.

Protect from light and store upright.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml: Drops are a clear to translucent yellow oily liquid with a slight earthy aroma and distinctive citrus flavour, packed in a black glass bottle with a black screw on graduated pipette.

Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml: Drops are a clear to translucent yellow oily liquid with a slight earthy aroma and distinctive mint flavour, packed in a black glass bottle with a black screw on graduated pipette.

Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml: Drops are a clear to translucent yellow oily liquid with a slight earthy aroma and distinctive cinnamon flavour, packed in a black glass bottle with a black screw on graduated pipette.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Young Living South Africa (Pty) Ltd
Clearwater Office Park, Building 6
Cnr of Christian de Wet and Mellenium Road
Strubensvalley, Roodepoort, Gauteng, 1724
https://www.youngliving.com/en_ZA

8. REGISTRATION NUMBER(S)

To be allocated.

Nature's Ultra CBD Drops is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use.

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

March 2020.

10. DATE OF REVISION OF THE TEXT

TBC

PATIENT INFORMATION LEAFLET

This leaflet tells you about **Nature's Ultra CBD Oil Drops**

Complementary Medicines. Health Supplement.

Scheduling Status: Not Scheduled

PROPRIETARY NAME AND DOSAGE FORM:

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml
Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml
Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml

Health Supplement:

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

Please Read all of this leaflet carefully because it contains important information for you. **Nature's Ultra CBD** is available without a doctor's prescription. Nevertheless, you still need to use **Nature's Ultra CBD Drops** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.
 Do not share **Nature's Ultra CBD Drops** with any other person.
 Ask your pharmacist if you need more information or advice.
 You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet:

1. What Nature's Ultra CBD Drops is and what it is used for.
2. What you need to know before you use Nature's Ultra CBD Drops.
3. How to use Nature's Ultra CBD Drops.
4. Possible side effects.
5. How to store Nature's Ultra CBD Drops.
6. Contents of the pack and other information Drops.

1. What Nature's Ultra CBD is used for:

Nature's Ultra CBD Drops may assist with the relief of pain and inflammation, stress, anxiety and sleeplessness related conditions.

2. What you need to know before you use Nature's Ultra CBD Drops:

Do not use Nature's Ultra CBD Drops:

- If you are hypersensitive (allergic) to CBD or any of the ingredients of **Nature's Ultra CBD Drops** (listed in section 6).
- If you are taking antidepressants or sleeping tablets.

Other medicines and Nature's Ultra CBD Drops:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional or herbal medicines.)

Do not take **Nature's Ultra CBD Drops** if you are taking antidepressant or ant-epileptic medication, as side effects of these medicines may be intensified.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your healthcare practitioner for advice before taking this medicine.

Driving and using machines:

Do not use **Nature's Ultra CBD Drops** if you are driving or operating heavy machinery as **Nature's Ultra CBD Drops** may cause drowsiness and sedation.

3. How to use Nature's Ultra CBD Drops:

Do not share medicines prescribed for you with any other person.
 Always use **Nature's Ultra CBD Drops** exactly as described in this leaflet or as advised by your healthcare practitioner. Do not exceed the recommended daily dose.

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml Take 1,0 ml orally once daily when necessary.
Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml Take 1,0 ml orally once daily when necessary.
Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml Take 1,0 ml orally once daily when necessary.

The safety and efficacy of **Nature's Ultra CBD Drops** in children has not yet been established.

If you take more Nature's Ultra CBD Drops than you should:

There are no known cases of overdose with CBD.
 In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Nature's Ultra CBD Drops:

Take your next dose at your regular time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects:

Nature's Ultra CBD Drops can have side effects. Not all side effects reported for **Nature's Ultra CBD Drops** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **Nature's Ultra CBD Drops**, please consult your healthcare practitioner for advice.

Nature's Ultra CBD Drops can cause drowsiness, fatigue and sedation. This is worse when taken at the same time as medicines with sedative properties, including herbal or traditional medicines.

Nature's Ultra CBD Drops can also cause a dry mouth, diarrhoea, weight loss, nausea, constipation and vomiting with high doses.

Reporting of side effects

If you get side effects, talk to your healthcare practitioner. 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 **Nature's Ultra CBD Drops**.

5. How to store Nature's Ultra CBD Drops:

Store in a cool, dry place at or below 25 °C. Store upright. Do not refrigerate. Keep out of reach of children. Return all unused medicine to your pharmacist.
 Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What Nature's Ultra CBD Drops contains:

The active ingredient is cannabidiol (CBD).

The other (inactive) ingredients are:

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml:

- Cocos nucifera (Coconut) oil, Citrus paradise (Grapefruit) peel oil, Citrus aurantium dulcis (Orange) peel oil, Organic Stevia rebaudiana (Stevia) leaf extract.

Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml

- Cocos nucifera (Coconut) oil, Mentha piperita (Peppermint) oil, Metha spicata (Spearmint) leaf extract, Organic Stevia rebaudiana (Stevia) leaf extract.

Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml

- Cocos nucifera (Coconut) oil, Cinnamomum zeilanicum (Cinnamon) bark oil, Organic Stevia rebaudiana (Stevia) leaf extract.

What Nature's Ultra CBD looks like and contents of the pack:

Nature's Ultra Citrus CBD Oil 500 mg Drops 30 ml: Drops are a clear to translucent yellow oily liquid with a slight earthy aroma and distinctive citrus flavour, packed in a black glass bottle with a black screw on graduated pipette.

Nature's Ultra Cool Mint CBD Oil 500 mg Drops 30 ml: Drops are a clear to translucent yellow oily liquid with a slight earthy aroma and distinctive mint flavour, packed in a black glass bottle with a black screw on graduated pipette.

Nature's Ultra Cinnamon CBD Oil 500 mg Drops 30 ml: Drops are a clear to translucent yellow oily liquid with a slight earthy aroma and distinctive cinnamon flavour, packed in a black glass bottle with a black screw on graduated pipette.

Holder of the certificate of registration:

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https://www.youngliving.com/en_ZA

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Nature's Ultra CBD Drops is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use.