

PATIENT INFORMATION LEAFLET FOR

Oxiprovin®

SCHEDULING STATUS:

S0

OXIPROVIN®, 140 mg capsules
Vitis vinifera (L.) (Grape seed extract)
Source of oligomeric proanthocyanidins
Sugar free

COMPLEMENTARY MEDICINE

Health Supplement

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

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

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

- OXIPROVIN® is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use OXIPROVIN® carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share OXIPROVIN® with any other person.
- Ask your doctor, pharmacist or other health care provider if you need more information or advice.
- If symptoms worsen or do not improve after 3 months of using OXIPROVIN®, a doctor, pharmacist or other health care provider should be consulted.

What is in this leaflet

1. What OXIPROVIN® is and what it is used for.
2. What you need to know before you take OXIPROVIN®.
3. How to take OXIPROVIN®.
4. Possible side effects.
5. How to store OXIPROVIN®.
6. Contents of the pack and other information.

1. What OXIPROVIN® is and what it is used for

OXIPROVIN® is a health supplement that contains grape seed extract which is a source of antioxidants (oligomeric proanthocyanidins) for the maintenance and preservation of good health and venous health.

2. What you need to know before you take OXIPROVIN® Do not take OXIPROVIN®:

- If you are hypersensitive (allergic) to the active substance, *Vitis vinifera* (L.) (grape and/or grape seed extract), or any of the other ingredients in OXIPROVIN® (listed in section 6).
- If you are having surgery, since OXIPROVIN® might increase your risk of bleeding and bruising. Tell your doctor that you are taking OXIPROVIN® who might recommend that you stop taking OXIPROVIN® for at least 2 weeks before the surgery.
- If you are younger than 18 years old (see Warnings and precautions).

Warnings and precautions

Take special care with OXIPROVIN®:

- In venous conditions, if there is inflammation of the skin, thrombophlebitis (inflammation in a vein caused by a blood clot) or firmness under the skin, severe pain, ulcers, sudden swelling of one or both legs, poor function of the heart or kidneys, a doctor should be consulted.
- If used for venous health and symptoms worsen or do not improve after 3 months of using OXIPROVIN®, a doctor, pharmacist or other health care provider should be consulted.
- If you are pregnant or breastfeeding, you should consult a health care practitioner before taking OXIPROVIN® (see Pregnancy and breastfeeding).

Children and adolescents:

OXIPROVIN® should not be used in patients younger than 18 years.

Other medicines and OXIPROVIN®:

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

- If you take blood thinning medicines. Taking OXIPROVIN® together with blood thinning medication may increase your risk of bleeding. Your health care provider might monitor your INR (International Normalised Ratio) more regularly.
- If you are taking any other medicines or supplements. Certain medicines are metabolised (processed) by your liver and OXIPROVIN® can change the level of these medicines in your blood. Your health care provider will help you to decide whether you may take OXIPROVIN® together with these medicine/supplements.
- If you are taking midazolam (e.g. for sleep (before surgery) and anxiety). The effect of midazolam may be decreased when you are taking OXIPROVIN® over a long period.

Pregnancy and breastfeeding:

The safety of OXIPROVIN® during pregnancy and breastfeeding has not been established (see Warnings and precautions).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking OXIPROVIN®.

Driving and using machinery:

It is not known if OXIPROVIN® may affect mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment.

It is not always possible to predict to what extent OXIPROVIN® may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware how OXIPROVIN® affects you.

3. How to take OXIPROVIN®

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

Always take OXIPROVIN® exactly as described in this leaflet or as your doctor, pharmacist or other health care provider have told you. Check with your doctor, pharmacist or other health care provider if you are not sure.

The usual dose is:

Adults over 18 years

For the maintenance of good health:

Take one (1) capsule daily.

For times of increased demand or for venous health:

Take 2 – 3 capsules daily.

For venous health, you should take OXIPROVIN® for at least one (1) month to see beneficial effects.

Method of administration

For oral use only.

Take with water.

If you take more OXIPROVIN® than you should:

In the event of overdosage, consult your doctor, pharmacist or other health care provider. If none is available, contact the nearest hospital or poison centre.

If you forget to take a dose of OXIPROVIN®:

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

OXIPROVIN® can have side effects.

Not all side effects reported for OXIPROVIN® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OXIPROVIN®, please consult your health care provider for advice.

If any of the following happens, stop taking OXIPROVIN® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to OXIPROVIN®. You may need urgent medical attention or hospitalisation.

Less frequent side effects of grape seed extract that have been documented occur at rates similar to placebo. Tell your doctor if you notice any of the following:

Less frequent side effects

- Headache
- Sore throat, cough, allergic rhinitis (itchy, watery eyes, sneezing), nasopharyngitis (the common cold, affecting the nose, throat, and sinuses)
- Bellyache (abdominal pain)
- Nausea
- Diarrhoea
- Joint pain
- Low back pain (lumbago)

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or other health care provider.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or health care provider. 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 OXIPROVIN®.

5. How to store OXIPROVIN®

- Store all medicines out of reach of children.
- Store at or below 25 °C in a cool, dry place.
- Store in the original package / container.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label / carton / bottle.
- 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 OXIPROVIN® contains

- The active substance is:
Each capsule contains:
Vitis vinifera (L.) (Grape seed extract) 140 mg
(Source of oligomeric proanthocyanidins)

The other ingredients are hard gelatine capsules (bovine gelatine, titanium dioxide), magnesium stearate and microcrystalline cellulose.

What OXIPROVIN® looks like and contents of the pack

White and clear, size no. 3 hard gelatine (bovine) capsules, filled with brown powder.

Packed in a white PP securitainer with a white, LDPE plastic closure and a tamper evident seal. Enclosed with a silica gel sachet and foam insert on top of the capsules. Pack sizes: 40, 60 or 120 capsules. Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD.
29 Victoria Link
Route 21 Corporate Park
Irene, 0178, RSA

This leaflet was last revised in:

March 2023

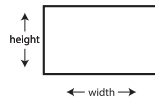
Registration number: Complementary medicine

Access to the corresponding Professional Information:

The professional information can be found on: www.oxiprovin.com

Oxiprovin 60 Capsules PIL - ENG

Date: 28/03/2023
Die Size: 210mm (wide) x 148mm (high)
Fold Size: 26.25mm (width) x 148mm (height)
Colours: 100% Black



PASIËNTINLIGTINGSPAMFLET VIR

Oxiprovin®

SKEDULERINGSSTATUS:

S0

OXIPROVIN®, 140 mg kapsules
Vitis vinifera (L.) (Druiwepitekstrak)
Bron van oligomeriese proantosianidien
Suikervry

KOMPLEMENTÊRE MEDISYNE

Gesondheidsaanvulling
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA vir kwaliteit, veiligheid of voorgestelde gebruik, geëvalueer nie.

“In Diët met ‘n wye verskeidenheid is die mees effektiewe en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling sowel as verstandelike en fisiese prestasie te verseker.

Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting

- OXIPROVIN® is beskikbaar sonder ‘n doktersvoorskrif om self jou gesondheid te handhaaf. Dit is nogtans belangrik om OXIPROVIN® met versigtigheid te gebruik om die beste resultate te verseker.
- Hou die pamflet om dit weer te lees.
- Moenie OXIPROVIN® met enige ander deel nie.
- Vra jou dokter, apteker of ander gesondheidsorgkundige indien jy meer inligting of advies benodig.
- Indien jou simptome vererger of nie verbeter nadat jy OXIPROVIN® vir drie maande geneem het nie, raadpleeg ‘n dokter, apteker of ander gesondheidsorgkundige.

Watter inligting is in hierdie pamflet

1. Wat OXIPROVIN® is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy OXIPROVIN® neem.
3. Hoe om OXIPROVIN® te neem.
4. Moontlike nuwe-effekte.
5. Hoe om OXIPROVIN® te berg.
6. Inhoud van die pakkie en ander inligting.

1. Wat OXIPROVIN® is en waarvoor dit gebruik word
OXIPROVIN® is ‘n gesondheidsaanvulling wat druiewepitekstrak bevat, ‘n bron van antioksidante (oligomeriese proantosianidien) vir die instandhouding en behoud van goeie gesondheid en venuseuse gesondheid.

2. Wat jy moet weet voordat jy OXIPROVIN® neem

- **Moenie OXIPROVIN® neem nie:**
 - Indien jy hipersensitief (allergies) is vir die aktiewe bestanddeel, *Vitis vinifera* (L.) (druif en/of druiewepitekstrak), of enige van die ander bestanddele in OXIPROVIN® (sien afdeling 6).
 - Indien jy vir ‘n operasie moet gaan, aangesien OXIPROVIN® jou risiko vir bloeding of kneusing mag verhoog. Sê daarom vir jou dokter dat jy OXIPROVIN® neem wat dan mag voorstel dat jy ten minste 2 weke voor die operasie

ophou om OXIPROVIN® te neem.

- Indien jy jonger as 18 jaar is (sien Waarskuwings en voorsorgmaatreëls).

Waarskuwings en voorsorgmaatreëls

Wees versigtig met OXIPROVIN®:

- In venuseuse toestande, indien daar velinflammasie, tromboflebitis (inflammasie in ‘n aar wat deur ‘n bloedklont veroorsaak is) of ‘n ferm area onder die vel is, of erge pyn, sere, skielike swelling van een of beide bene, swak funksionering van die hart of niere, moet ‘n dokter geraadpleeg word.
- Indien gebruik vir venuseuse gesondheid en jou simptome vererger of verbeter nie nadat jy OXIPROVIN® vir 3 maande geneem het nie, moet jy ‘n dokter, apteker of ander gesondheidsorgkundige raadpleeg.
- Indien jy swanger is of borsvoed, raadpleeg ‘n gesondheidsorgkundige voordat jy OXIPROVIN® neem (sien Swangerskap en borsvoeding).

Kinders en adolessente:

- Indien jy jonger as 18 jaar is, moet jy nie OXIPROVIN® neem nie.

Ander medisyne en OXIPROVIN®:

- Lig altyd jou gesondheidsorgkundige in as jy enige ander medisyne gebruik (dit sluit alle komplementêre of tradisionele medisyne in).
- Indien jy medisyne vir bloedverdunding gebruik. As jy OXIPROVIN® saam met die medisyne neem, mag jou kans vir bloeding verhoog. Jou gesondheidsorgkundige mag jou INR (Internationale Genormaliseerde Verhouding) meer gereeld toets.
 - Indien jy ander medisyne of aanvullers gebruik. Sommige medisyne word in jou lewer gemetaboliseer (verwerk) en OXIPROVIN® kan die konsentrasie van die medisyne in jou bloed verhoog of verlaag. Jou gesondheidsorgkundige kan jou help om te besluit of jy OXIPROVIN® saam met die medisyne/aanvullers kan gebruik.
 - Indien jy midazolam (bv. vir slaap (voor ‘n operasie) en angstigheid) neem. Wanneer jy OXIPROVIN® oor ‘n lang tydperk neem, kan die effek van midazolam verlaag word.

Swangerskap en borsvoeding:

Die veiligheid van OXIPROVIN® tydens swangerskap en borsvoeding is nie vasgestel nie (sien Waarskuwings en voorsorgmaatreëls).

Indien jy swanger is of borsvoed, vermoed jy is swanger of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige om advies voordat jy OXIPROVIN® neem.

Bestuur en die gebruik van masjinerie:

Dit is nie bekend of OXIPROVIN® ‘n effek mag hê op die verstandelike en/of fisiese vermoë om enige taak of aktiwiteit uit te voer wat verstandelike fokus, oordeel en/of goeie koördinasie en sig vereis nie, bv. bestuur, rykuns, vlieg, seil of die hantering van masjinerie/toerusting.

Dit is nie altyd moontlik om te voorspel in watter mate OXIPROVIN® met jou daaglikse aktiwiteite mag inmeng nie. Maak asseblief seker dat jy nie bogenoemde aktiwiteite beoefen voordat jy weet in hoe ‘n mate OXIPROVIN® jou beïnvloed nie.

3. Hoe om OXIPROVIN® te neem

Moenie medisyne wat vir jou voorgeskryf is, met ‘n ander persoon deel nie.

Neem altyd OXIPROVIN® presies soos wat dit in hierdie pamflet beskryf is of soos jou dokter, apteker of ander gesondheidsorgkundige aanbeveel het. Bevestig met jou dokter, apteker of ander gesondheidsorgkundige indien jy onseker is.

Die gewone dosis is:

Volwassenes bo 18 jaar

Vir die instandhouding van goeie gesondheid:

Neem een (1) kapsule per dag.

In tye van verhoogde behoefte of vir venuseuse gesondheid:

Neem 2 – 3 kapsules per dag.

Vir venuseuse gesondheid, neem OXIPROVIN® vir ten minste een (1) maand om voordelige effekte te sien.

Toedieningsmetode

Vir orale gebruik alleenlik.

Neem met water.

Indien jy meer OXIPROVIN® inneem as wat voorgeskryf is:

In geval van oordosering, raadpleeg jou dokter, apteker of ander gesondheidsorgkundige. Indien nie een beskikbaar is, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om ‘n dosis OXIPROVIN® te neem:

Moenie ‘n dubbele dosis neem om op te maak vir die vergeete individuele dosis nie.

4. Moontlike nuwe-effekte

OXIPROVIN® kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir OXIPROVIN® aangemeld is, word in hierdie pamflet genoem nie. Indien jou algemene gesondheid agteruitgaan, of jy ondervind enige ongewensde simptome terwyl jy OXIPROVIN® gebruik, raadpleeg asseblief jou gesondheidsorgkundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van OXIPROVIN® en lig jou dokter onmiddellik in, of gaan na die ongevallenafdeling van die naaste hospitaal:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik maak om te sluk of asem te haal.
 - Veluitslag of jeuk.
 - Hoofpyn.
 - Floute.
- Hierdie is almal baie ernstige nuwe-effekte. Indien jy enige daarvan ervaar, het jy moontlik ‘n ernstige allergiese reaksie op OXIPROVIN®. Jy benodig moontlik dringende mediese behandeling of hospitalisasie.

Minder frekwente nuwe-effekte van druiewepitekstrak wat gedokumenteer is, kom in dieselfde mate as ‘n placebo voor. Lig jou dokter in as jy enige van die volgende ervaar:

Minder algemene nuwe-effekte

- Seer keel, hoes, allergiese rinitis (jeukerige, waterige oë, nies), nasofaringitis (verkoue, wat jou neus, keel en sinusse affekteer)
- Maagpyn (buikpyn)
- Naarheid
- Diarree

- Gewrigspyn
- Laerugpyn (rugig)

Indien jy enige nuwe-effekte ervaar wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter, apteker of ander gesondheidsorgkundige in.

Aanmelding van nuwe-effekte:

Indien jy nuwe-effekte ervaar, raadpleeg jou dokter, apteker of ander gesondheidsorgkundige. Jy kan nuwe-effekte ook aan SAHPRA rapporteer via die “**6.04 Adverse Drug Reaction Reporting Form**”, wat aanlyn onder SAHPRA se publikasies verskyn: <https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van OXIPROVIN® te verskaf.

5. Hoe om OXIPROVIN® te berg

- Berg alle medisyne buite bereik van kinders.
- Berg teen of onder 25 °C in ‘n koel, droë plek.
- Berg in die oorspronklike verpakking / houër.
- Moenie in ‘n backkamer berg nie.
- Moenie ná die vervaldatum op die etiket / karton / bottel gebruik nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat OXIPROVIN® bevat

Die aktiewe bestanddeel is:

Elke kapsule bevat:

Vitis vinifera (L.) (Druiwepitekstrak) 140 mg

(Bron van oligomeriese proantosianidien)

Die ander bestanddele is harde gelatienekapsule (bovine gelatien, titaandiksidie), magnesiumstearaat en mikrokristallyne sellulose.

Hoe OXIPROVIN® lyk en die inhoud van die verpakking

Wit en deurskynende no. 3 harde gelatienekapsule (bovine), gevul met bruin poeier.
Verpakkings in ‘n wit PP-sekuriiteitshouer met ‘n wit LDPE-plastiese sluiting en peuterbestande seël. Geseël met ‘n silika gel sakkie en spons insetsel bo op die kapsules.

Verpakkings: 40, 60 of 120 kapsules.

Nie alle verpakkings word noodwendig bemark nie.

Houer van Registrasiesertifikaat

PHARMACORP (EDMS) BPK.

29 Victoria Link

Route 21 Corporate Park

Irene, 0178, RSA

Hierdie pamflet is voorheen hersien in:

Maart 2023

Registrasienuommer: Komplementêre Medisyne

Toegang tot die ooreenstemmende Professionele Inligting:

Die professionele inligting is beskikbaar by:

www.oxiprovin.com

Oxiprovin 60 Capsules PIL - AFR

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