

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **SO**

OVARIA SACHETS (Peach/Orange)

Active substances per sachet:

4 000mg Inositol (as Myo-Inositol)
2mg Chromium Nicotinate Glycinate Chelate (2.5%)

Sugar free

Category DS: 32.16, Other, Complimentary Human Medicines
Discipline Specific Combination 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

- Keep this leaflet. You may need to read it again.
- OVARIA is available without a doctor's prescription.
- Nevertheless you still need to use OVARIA careful to get the best results from it.
- Do not share OVARIA with other people.
- If you have further questions, please ask your doctor, pharmacist nurse or other health care provider.

1. What is OVARIA and what is it used for

- OVARIA is a nutritional supplement for optimal ovarian health in women with Polycystic Ovary Syndrome (PCOS).
- What is PCOS?*
- Polycystic Ovarian Syndrome (PCOS) is a common endocrine (hormone), metabolic and reproductive disorder.
- According to the Rotterdam diagnostic criteria, PCOS is diagnosed when a female of reproductive age presents with two of three criteria:
 1. Oligomenorrhea (infrequent menstrual periods) or amenorrhoea (absent menstrual period without an known underlying cause),
 2. Excess androgen activity (hirsutism (60-83% of PCOS sufferers)1 - excess hair growth, acne (11-43% of PCOS sufferers)1, seborrhoea - excess sebum secretion on the skin),
 3. Polycystic ovaries (with typical features at gynaecological ultrasound). The presence of cysts alone does not establish the diagnosis.
- Ovaria contains Myo-inositol (a naturally occurring substance found in all living cells) and Chromium Nicotinate Glycinate Chelate.
- When taken at the recommended dose, Ovaria provides 50mcg of chromium (the recommended daily amount) and 4g of myo-inositol.

Myo-Inositol (MI):

- Plays an important role as the structural basis for a number of secondary messengers in eukaryotic cells, including inositol phosphates, phosphatidylinositol (PI) and phosphatidylinositol phosphate (PIP) lipids.
- MI therapy reduces fasting glucose levels as well as the HOMA index (a measure of insulin resistance)
- MI causes a significant increase in SHBG (after 24 weeks of therapy), this reduces free testosterone levels in the blood.
- MI supplementation increases ovulation rate in anovulatory women.
- 30% of patients established normal ovarian rhythms (three or more ovulations) through a 16 week period.
- MI significantly decreases levels of total androgen, total testosterone, free testosterone and serum DHEA. All significantly reduced in anovulatory women with PCOS.
- There were no differences between MI and DCI (D-Chiro-Inositol) in any of these outcomes.
- MI reduces hirsutism by 29% after 6 months (Ferriman-Gallway score).
- MI produced a 59% reduction of severe acne after 6 months of therapy in women with PCOS.

Chromium Nicotinate Glycinate Chelate:

- Chromium is an essential element in glucose and insulin homeostasis.
- Chromium supplementation in women with PCOS significantly decreases serum insulin levels, homeostasis model of assessment-insulin resistance (HOMA-IR) and homeostatic model assessment-beta cell function (HOMA-B).
- Chromium significantly increases the quantitative insulin sensitivity check index (QUICKI) score.

2. What you need to know before you take OVARIA

Do not take OVARIA if you are hypersensitive (allergic) to Inositol or Chromium or any of the other ingredients of OVARIA.

Warnings and precautions

- If you are on any medication or suffering from any medical condition, it is advisable to seek medical advice before starting any new medicine.
- Nutritional supplements should not be used as a substitute for a varied diet or healthy lifestyle.

Children and adolescents

- There is no clinical data to support the use of OVARIA in pre-reproductive age in females.

Other medicines and OVARIA

- While folic acid is generally considered essential for anyone that's trying to conceive or already pregnant, a common genetic disorder known as the MTHFR gene mutation can mean that folic acid can potentially be harmful to both you and your baby.
- Rather than taking folic acid supplements, women with this gene mutation instead need to take the active form of folate, known as methyl folate or 5-MTHF.
- If you are going to take folic acid it's important that you get tested for this gene mutation. And if you have it make sure to find a competent doctor that can supervise your 5-MTHF dosage rates as these need to be monitored to avoid adverse side effects.
- There is no evidence to show any negative interaction with medicines.
- When taking any dietary supplement alongside other medication, it is always advisable to consult your doctor/ pharmacist.

Pregnancy, breastfeeding and fertility

- Although data exists and clinical trials has been done to proof the safety and efficacy in pregnancy and breastfeeding, it is still advisable to consult your doctor, pharmacist or other health care provider for advice if you want to start taking OVARIA when you are planning to have a baby or are pregnant or breastfeeding.

3. How to take OVARIA

- The usual dose is one (1) sachet dissolved in a glass of water or juice with breakfast once a day.
- Mix the contents of one sachet in a glass of water or other beverage.
- Stir well until completely dissolved before drinking.
- Take OVARIA once a day, every day, at about the same time each day.
- Taking your medicine at the same time each day will help you remember to take it.
- See Section 6 for usage instructions on label.
- Do not share medicines prescribed for you with any other person.
- Always take OVARIA exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your health practitioner if you are not sure.
- Established through clinical trials patients will start seeing positive results after as little as 3 months.
- Consult a health practitioner if you are on any other medication, are pregnant or breastfeeding or if you experience any side effects while taking OVARIA.
- Do not exceed recommended amount.
- If you take more OVARIA than you should*
- In the event of over dosage, consult your doctor or pharmacist.
- If neither is available, contact the nearest hospital or poison control centre.

If you forget to take OVARIA

Take a dose as soon as you remember.

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

If you stop taking OVARIA

There is no known data available for withdrawal or any other effects when treatment is interrupted or ended early.

4. Possible side effects

OVARIA can have side effects.

No serious side effects or intolerance problems were reported or observed.

You can experience nausea if you exceed the dosage

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

Should your general health worsen or if you notice any side effects not mentioned in this leaflet while taking OVARIA, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects directly to medical@lamelle.co.za

Additionally, online <https://www.sahpra.org.za/Publications/Index/8> under SAHPRA's publications, you will find SAHPRA "6.04 Adverse Drug Reaction Reporting Form"

By reporting side effects, you can help provide more information on the safety of OVARIA.

5. How to store OVARIA

- Store all medicines out of reach of children.
- Store in the original package
- Store in a cool, dry place below 25°C.
- Protect from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Do not use OVARIA if you notice visible colour or composition changes.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems.

6. Contents of the pack and other information

- The active substances in Ovaria are 4 gram Inositol (as Myo-Inositol) and 2mg Chromium Nicotinate Glycinate Chelate 2.5% (50ug elemental Chromium).
- The other ingredients are Aerosil® 200 Pharma, TSL Orange J1431 and TSL Peach Yellow J1391.
- See Section 3 for usage instructions.

USAGE INSTRUCTIONS

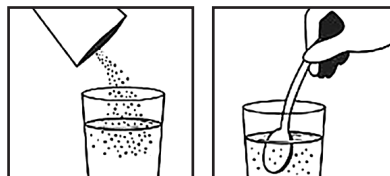
Suggested Use: Take one sachet per day. Mix powder with water or other beverages.

Consume with or in between meals. Stir well until completely dissolved before drinking.

What OVARIA looks like and contents of the pack

There are two Flavours available

- OVARIA (Orange)
Orange coloured carton containing 30 orange coloured sachets with dry white, orange-flavoured powder.
Mass of contents in each sachet is 4182 gram.
- OVARIA (Peach)
Pink coloured carton containing 30 pink coloured sachets with dry white, peach-flavoured powder.
Mass of contents in each sachet is 4182 gram.



Holder of Certificate of Registration

Lamelle Pharmaceuticals (Pty) Ltd
Building C1, Northlands Deco Park,
Newmarket Road, North Riding

Application number

OVARIA (Orange): D552041
OVARIA (Peach): D552042

This leaflet was last revised

March 2021

PASIËNT INLIGTINGS PAMFLET

SKEDULERINGS STATUS: **SO**

OVARIA SAKKIES (Perske/Lemoen)

Aktiewe bestanddele per sakkie:

4 000mg Inositol (as Myo-Inositol)
2mg Chromium Nicotinate Glycinate Chelate (2.5%)

Suikervry

Kategorie DS: 32.16, Ander, Komplimentêre Medisyne vir menslike gebruik
Disiplinespesifieke Kombinasie Gesondheidsaanvullings

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

LEES HIERDIE PAMFLET NOUKEURIG DEUR WANT DIT HOU BELANGRIKE INLIGTING VIR U IN

- Bewaar hierdie pamflet, want u gaan dit waarskynlik weer lees.
- OVARIA is sonder 'n doktersvoorskrif beskikbaar.
- U moet OVARIA egter steeds versigtig gebruik om die beste resultate daaruit te kry
- Moenie OVARIA met ander mense deel nie.
- As u verdere vrae het, kan u dit vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.

1. Wat is OVARIA en waarvoor word dit gebruik?

- OVARIA is 'n voedingsaanvulling vir optimale ovariale gesondheid vir vroue met polististiese ovarium sindroom (PCOS).
- Wat is PCOS?*
- Polististiese ovariumsindroom (PCOS) is 'n algemene endokriene (hormoon), metaboliese en reprodutiewe versteuring.
- Volgens die Rotterdamse diagnostiese kriteria word PCOS gediagnoseer as 'n vrou van reprodutiewe ouderdom twee van drie kriteria het:
 - Oligomenorree (ongereelde menstruasieperiodes) of amenoree (afwesige menstruasieperiode sonder 'n bekende onderliggende oorsaak),
 - Oormatige androgeenaktiwiteit (hirsutisme (60-83% van PCOS-lyers) - oormatige haargroei, aknee (11-43% van PCOS-lyers), seborrhoea - oortollige sebumsekresie op die vel),
 - Polististiese eierstokke (met tipiese kenmerke by ginekologiese ultraklank). Die aanwesigheid van siste alleen bevestig nie die diagnose nie.
- OVARIA bevat myo-inositol ('n natuurlike stof wat in alle lewende selle voorkom) en chromium nicotinate glycinate chelate.
- Wanneer OVARIA volgens die aanbevole dosis geneem word, voorsien dit 50mcg chromium (die aanbevole daaglikse hoeveelheid) en 4g myo-inositol.

Myo-Inositol (MI):

- Speel 'n belangrike rol as die strukturele basis vir 'n aantal sekondêre boodskappers in eukariotiese selle, insluitend inositolfosfate, fosfatidielinositol (PI) en fosfatidielinositolfosfaat (PIP) lipiede.
- MI-terapie verlaag die vastende glukosevlakke sowel as die HOMA-indeks ('n maatstaf vir insulienweerstandigheid).
- MI veroorsaak 'n beduidende toename in SHBG (na 24 weke van behandeling), dit verminder die vrye testosteroonvlakke in die bloed.
- MI-aanvulling verhoog die ovulasietempo by anovulatoriese vroue.
- 30% van die pasiënte het normale ovariale ritmes (drie of meer ovulasies) ontwikkel gedurende 'n periode van 16 weke.
- MI verlaag die vlakke van totale androgeen, totale testosteroon, vrye testosteroon en serum DHEA aansienlik. Almal is aansienlik verminderd by anovulatoriese vroue met PCOS.
- Daar was geen verskille tussen MI en DCI (D-Chiro-Inositol) in een van hierdie uitkomstige nie.
- MI verminder hirsutisme in vroue met PCOS na 6 maande met 29% (Ferriman-Gallway-telling).
- MI het 'n vermindering van 59% van ernstige aknee opgelewer na 6 maande se behandeling by vroue met PCOS.

Chromium Nicotinate Glycinate Chelate:

- Chromium is 'n noodsaaklike element in glukose- en insulien-homeostase.
- Chromiumaanvulling by vroue met PCOS verlaag die insulienvlakke van serum, die homeostasie-model van assessering-insulienweerstand (HOMA-IR) en die homeostatiese model-assessering-beta-selfunksie (HOMA-B).
- Chromium verhoog die kwantitatiewe telling vir die insulien sensitiviteitstoetsindeks (QUICKI).

2. Wat u moet weet voordat u OVARIA neem

Moenie OVARIA neem as u oorgevoelig (allergies) is vir enige van die bestanddele van OVARIA nie.

Waarskuwings en voorsorgmaatreëls

- As u enige medikasie gebruik of aan enige mediese toestand ly, is dit raadsaam om mediese advies in te win voordat u met 'n nuwe medisyne begin.
- Voedingsaanvullings moet nie as 'n plaasvervanger vir 'n gevarieerde dieet of gesonde leefstyl gebruik word nie

Kinders en adolessente

- Daar is geen kliniese data wat die gebruik van OVARIA by vroue in die pre-reprodutiewe ouderdom ondersteun nie.

Ander medisyne en OVARIA

- Alhoewel foliensuur oor die algemeen as noodsaaklik beskou word vir almal wat swanger wil raak of reeds swanger is, kan 'n algemene genetiese afwyking, bekend as die MTHFR-geenmutasie, beteken dat foliensuur moontlik vir u en u baba skadelik kan wees.
- In plaas daarvan om foliensuuraanvullings te neem, moet vroue met hierdie geenmutasie eerder die aktiewe vorm van folaat, bekend as metielfolaat of 5-MTHF, neem. As u foliensuur gaan gebruik, is dit belangrik dat u vir hierdie geenmutasie getoets word.
- As u dit het, moet u 'n bekwame dokter vind wat toesig kan hou oor u dosisse van 5 MTHF, aangesien dit gemonitor moet word om nadelige nuwe-effekte te voorkom.
- Daar is geen bewyse dat OVARIA enige negatiewe interaksie met ander medisyne toon nie.
- As u enige aanvulling saam met ander medisyne inneem, is dit altyd raadsaam om u dokter / apteker te raadpleeg.

Swangerskap, borsvoeding en vrugbaarheid

- Alhoewel daar data bestaan en kliniese toetse gedoen is om die veiligheid en doeltreffendheid van swangerskap en borsvoeding te bewys, is dit steeds raadsaam om u dokter, apteker of ander gesondheidsorgverskaffer te raadpleeg vir advies as u OVARIA wil begin gebruik terwyl u beplan om 'n baba te kry, swanger is of borsvoed.

3. Hoe om OVARIA te neem

- Die gewone dosis is een (1) sakkie wat een keer per dag in 'n glas water of vrugtesap opgelos en saam met ontbyt geneem word.
- Meng die inhoud van een sakkie in 'n glas water of ander vloeistof.
- Roer goed totdat dit heeltemal opgelos is voordat dit gedrink word.
- Neem OVARIA een keer per dag, elke dag, op ongeveer dieselfde tyd elke dag.
- As u die medisyne elke dag op dieselfde tyd neem, sal dit u help onthou om dit te gebruik.
- Sien Afdeling 6 vir gebruiksaanwysings op die etiket.
- Moenie medisyne wat vir u voorgeskryf is, met iemand anders deel nie.
- Neem OVARIA altyd presies soos voorgeskryf in hierdie pamflet of soos u dokter, apteker of verpleegster vir u voorgeskryf het. Raadpleeg u dokter as u nie seker is nie.
- Soos bewys deur kliniese toetse sal pasiënte na so min as drie maande positiewe resultate sien.
- Raadpleeg 'n geneesheer as u enige ander medisyne gebruik, swanger is of borsvoed, of as u enige nuwe-effekte ervaar wanneer u OVARIA gebruik.
- Moenie die aanbevole dosis oorskry nie.

As u meer OVARIA neem as wat u behoort te gebruik

- Raadpleeg u dokter of apteker in geval van 'n oordosis.
- Indien niemand beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As u vergeet om OVARIA te neem

- Neem 'n dosis sodra u dit onthou.
- Moenie 'n dubbele dosis neem om vir die vergete dosis op te maak nie.

As u die gebruik van OVARIA staak

- Daar is geen data beskikbaar vir wanneer die behandeling van OVARIA onderbreek of gestaak word nie.

4. Moontlike nuwe-effekte

OVARIA kan nuwe-effekte hê.

- Geen ernstige nuwe-effekte of onverdraagsaamheidsprobleme is gerapporteer of waargeneem nie.
- U kan naardeel ervaar as u die dosis oorskry.
- Nie alle nuwe-effekte wat vir OVARIA gerapporteer is, is in hierdie pamflet ingesluit nie.
- As u algemene gesondheid versleg, of as u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word terwyl u OVARIA neem nie, moet u u dokter of apteker daarvan in kennis stel.

Aanmelding van nuwe-effekte

- Raadpleeg u dokter, apteker of verpleegster as u nuwe-effekte ondervind.
- U kan nuwe-effekte ook direk aanmeld by medical@lamelle.co.za.
- Daarbenewens, aanlyn <https://www.sahpra.org.za/Publications/Index/8> onder SAHPRA se publikasies, vind u SAHPRA "6.04 Ongunstige geneesmiddelreaksie Verslagvorm"
- Deur nuwe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van OVARIA te verskaf.

5. Hoe om OVARIA te bêre

- Hou alle medisyne buite bereik van kinders.
- Bêre in die oorspronklike verpakking.
- Bêre dit op 'n koel, droë plek onder 25°C.
- Beskerm teen lig en vog.
- Moet nie in 'n badkamer bêre nie.
- Moet dit nie gebruik na die vervaldatum wat op die etiket aangedui word nie.
- Moenie OVARIA gebruik as u sigbare kleur- of samestellingsveranderings opmerk nie.
- Handig alle ongebruikte medisyne by u aptek in.
- Moenie ongebruikte medisyne weggooi in drein of rioolstelsels nie.

6. Inhoud van die verpakking en ander inligting

- Die aktiewe bestanddele in OVARIA is 4 gram inositol (as Myo-Inositol) en 2 mg Chromium Nicotinate Glycinate Chelate 2,5% (50 ug elementêre chroom).
- Die ander bestanddele is Aerosil® 200 Pharma, TSL Orange J1431 en TSL Peach Yellow J1391.
- Sien Afdeling 3 vir gebruiksaanwysings.

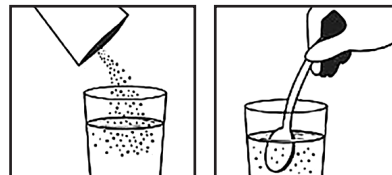
GEBRUIKSAANWYSINGS

Voorgestelde gebruik: Neem een sakkie per dag. Meng die poeier met water of ander vloeistof. Neem saam met of tussen maaltye. Roer goed totdat dit heeltemal opgelos is voordat dit gedrink word.

Hoe OVARIA lyk en die inhoud van die verpakking

Daar is twee geure beskikbaar:

- OVARIA (Lemoen)
Oranje gekleurde kartonhouer met 30 oranjegekleurde sakkies met droë wit, lemoengeur poeier.
Die inhoudsmassa van elke sakkie is 4182 gram.
- OVARIA (Perske)
Pienk gekleurde kartonhouer met 30 pienk gekleurde sakkies met droë wit, perskegeur poeier.
Die inhoudsmassa van elke sakkie is 4182 gram.



Houer van Registrasiesertifikaat

Lamelle Pharmaceuticals (Edms.) Bpk.
Gebou C1, Northlands Deco Park,
Newmarketweg, North Riding

Aansoeknommer

OVARIA (Lemoen): D552041
OVARIA (Perske): D552042

Hierdie pamflet is laas hersien

Maart 2021