PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
To be assigned

PMX™ Film-coated Tablets & Soft-Gel Capsules
Sucrose, Lactose, Gluten and Tartrazine Free

Complementary Medicine – Health Supplement

Read this leaflet carefully because it contains important information for you

PMX™ is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use PMX™ carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share PMX™ with any other person.
- Ask your healthcare professional or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What PMX™ is and what it is used for

PMX™ is a health supplement intended to support the symptoms associated with Premenstrual syndrome in young females.

2. What you need to know before you take PMX™

Do not take PMX™ if:
You experience a Hypersensitivity (allergic reaction) to any of the ingredients of PMX™ (as listed below in section 6).

You suffer from:
- conditions associated with hypercalcaemia and hypercalciuria, and renal impairment (chronic);
- renal osteodystrophy with hyperphosphataemia (risk of metastatic calcification);
- a Fish allergy.

Consult a qualified healthcare professional prior to use if you have renal/kidney disease, or a seizure disorder.

The Soft-Gel capsule may contain traces of soybeans, fish and products thereof.

Other medicines and PMX™
Always tell your healthcare professional if you are taking any other medicines. This includes complementary or traditional medicines.

Take PMX™ 2 hours before or after taking other medications or natural health products.

High dose zinc supplementation may cause a copper or iron deficiency.

Vitamin D may increase the risk of hypercalcaemia.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

The safety of the Evening Primrose Oil contained in PMX™ as listed below in section 6 has not been established in pregnancy and breastfeeding.

Driving and using machines
PMX™ does not have any effect on the ability to drive or the use of machinery.

3. How to take PMX™

Do not share medicines with any other person.
Always take PMX™ exactly as described in this leaflet or as your doctor, pharmacist or healthcare professional has told you. Check with your doctor or pharmacist if you are not sure.

The usual daily dosage of PMX™ is one tablet in the morning with breakfast and one soft-gel capsule at night with a meal.

Take PMX™ 2 hours before or after taking other medications including other natural health products.

PMX™ should be taken daily for as long as your healthcare professional indicates you to use it.

PMX™ should not be given to children below the age of 12 years (due to the Folate and Evening Primrose Oil content) unless under the direct supervision of a qualified healthcare professional.

If you take more PMX™ than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact your nearest hospital or poison centre.

If an overdose is suspected, PMX™ should be stopped immediately.

Treatment is generally symptomatic and supportive.

If you forget to take PMX™
Do not take a double dose of PMX™ to make up for a forgotten individual dose.

4. Possible side effects

PMX™ can have side effects in exceptional instances.

Not all side effects reported for PMX™ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PMX™ please consult your healthcare professional for advice.

Less frequent side effects:
- nausea (feeling sick)
- diarrhoea
- constipation
- indigestion
- bloating
- flatulence

Reporting of adverse reactions:
Should you notice any side effects not mentioned in this leaflet, please report it to AnaStellar Brands (Pty) Ltd via pharmacist@anastellar.co.za, (011) 792 4601 or https://anastellar.co.za.
By reporting side effects, you can help provide more information on the safety of PMX™.

5. How to store PMX™

Store all medicines out of reach of children.
Store at or below 25 °C.
Protect from light and moisture.
Store in the original container.
Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What PMX™ contains

PMX™ contains 2 Components:

Component 1
Each Pink Tablet contains:

Vitamin B6 derived from Pyridoxal-5-Phosphate Monohydrate 54 mg	**50**	**mg**
Vitamin B12 derived from Methylcobalamin 50 µg	**50**	**µg**
Vitamin D3 derived from Cholecalciferol 10 mg	**1 000**	**IU**
Biotin	**100**	**µg**
Folate derived from (6S)-5-Methyltetrahydrofolate 226 µg	**200**	**µg**
Inositol derived from Myo-Inositol 100 mg D-Chiro-Inositol 2,5 mg	**102,5**	**mg**
Iron derived from Ferrous Bisglycinate 25 mg	**5**	**mg**
Magnesium derived from Magnesium Oxide 332 mg	**200**	**mg**
Zinc derived from Zinc Oxide 25 mg	**20**	**mg**

All minerals are expressed in their elemental and non-elemental forms.

The other ingredients are:

Tablet Core - Calcium Phosphate Dibasic, Magnesium Stearate, Povidone, Silicon Dioxide, Solvent 45, Sodium Starch Glycolate

Tablet Coating - Castor Oil, Flexicoat Pink, Shellac

Component 2
Each Soft-Gel Capsule contains:

Evening Primrose Oil (*Oenothera biennis*) 65 – 85% Linoleic Acid 9% Gamma-Linoleic Acid [Seed]	**500**	**mg**
Vitamin E derived from d-α-Tocopherol Acetate 200 mg	**200**	**IU**

The other ingredients are Gelatin (Fish origin) and Glycerol.

What PMX™ looks like and contents of the pack

PMX™ contains an oval shaped Pink Film-coated Tablet and a clear shell oval shaped Soft-Gel Capsule filled with a Yellow coloured oily liquid.

Each pack contains 3 x PVC/PVDC/Aluminium blister strips with 10 x tablets contained in each strip as well as 3 x PVC/PVDC/Aluminium blister strips with 10 x Soft-Gel capsules contained in each strip.
The 6 x blister strips are enclosed within a cardboard carton.

Holder of Certificate of Registration

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Registration Number

To be assigned

This leaflet was last revised in January 2023

The Professional Information leaflet is available on https://anastellar.co.za

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

PASIËNT-INLIGTINGSPAMFLET

SKEDULERINGSTATUS
Moet toegeken word

PMX™ Filmbedekte Tablette en Sagtejel-kapsules Sukrose-, Laktose-, Gluten- en Tartrasienvry

Aanvullende Middels – Gesondheidsaanvulling

Lees hierdie pamflet sorgvuldig want dit bevat belangrike inligting vir jou

PMX™ is sonder ʼn doktersvoorskrif aan jou beskikbaar om jou gesondheid in stand te hou. Nogtans moet jy bedagsaam wees wanneer jy PMX™ gebruik om die beste resultate daarvan te kry.

- Hou hierdie pamflet, want dit mag dalk nodig wees om dit weer te lees.
- Moenie PMX™ met iemand anders deel nie.
- Vra jou gesondheidspraktisyn of apteker as jy meer inligting of advies benodig.

Wat is in hierdie pamflet

1. Wat PMX™ is en waarvoor dit gebruik word.
2. Wat jy moet weet voordat jy PMX™ neem.
3. Hoe om PMX™ te neem.
4. Moontlike newe-effekte.
5. Hoe om PMX™ te bewaar.
6. Die inhoud van die kartondosie en ander inligting.

1. Wat PMX™ is en waarvoor dit gebruik word

PMX™ is ʼn gesondheidsaanvulling met die doel om ondersteuning aan jong vroue te bied vir die simptome wat met Premenstruele sindroom geassosieer is.

2. Wat jy moet weet voordat jy PMX™ neem

Moenie PMX™ gebruik indien:
Jy ʼn Hipersensitiwiteit (allergiese reaksie) vir enige van die bestanddele van PMX™ toon nie (word in afdeling 6 aangegee).

Jy ly aan:

- toestande geassosieer met hiperkalsemie en hiperkalsiurie, en aan nierontoereikendheid (kronies);
- nier-osteodistrofie met hiperfosfatemie (risiko van metastatiese kalsifisering);
- of ʼn allergie vir Vis het nie.

Raadpleeg 'n gekwalifiseerde gesondheidsdeskundige indien jy 'n niersiekte het of sukkel met epileptiese aanvalle.

Die Sagtejel-kapsule kan spore van sojabone, vis en verwante produkte bevat.

Ander medisyne en PMX™
Vertel altyd vir jou gesondheidsdeskundige as jy enige ander medisyne neem. Dit sluit gesondheidsaanvullings of tradisionele medisyne in.

Neem PMX™ 2 uur voor of na jy enige ander medikasies of natuurlike gesondheidsprodukte geneem het.

ʼn Hoë-dosis Sinkaanvulling mag moontlik ʼn koper- of ystergebrek veroorsaak.

Vitamien D mag die risiko van hiperkalsemie verhoog.

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of borsvoed, dink dat jy swanger mag wees of beplan om ʼn baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsdeskundige voordat jy hierdie medisyne neem.

Die veiligheid van Nagblomolie soos deur PMX™ bevat en hieronder in afdeling 6 aangegee, is nie bepaal tydens swangerskap en borsvoeding nie.

Motorbestuur en die gebruik van masjinerie
PMX™ het nie ʼn effek op die vermoë om te bestuur of wanneer ʼn persoon masjinerie hanteer nie.

3. Hoe om PMX™ te neem

Moenie enige medisyne met iemand anders deel nie.
Neem PMX™ altyd presies soos in hierdie pamflet beskryf of soos jou dokter, apteker of ander gesondheidsdeskundige jou aanbeveel het. Vra jou dokter of apteker as jy nie seker is nie.

Die gewone daaglikse dosis van PMX™ is een tablet soggens met ontbyt en een sagtejel-kapsule saans met aandete.

Neem PMX™ 2 uur voor of na jy ander medikasies of natuurlike gesondheidsprodukte geneem het.

PMX™ moet daagliks geneem word vir so lank as wat jou gesondheidspraktisyn dit aanbeveel het.

PMX™ behoort nie aan kinders onder die ouderdom van 12 jaar gegee te word nie (vanweë die Folaat- en Nagblomolie-inhoud), tensy onder die direkte toesig van ʼn gekwalifiseerde gesondheidsdeskundige.

As jy meer PMX™ neem as wat jy moes
In die geval van ʼn oordosering, raadpleeg jou dokter of apteker. As nie een van die twee beskikbaar is nie, kontak jou naaste hospitaal of gifbeheersentrum.

As ʼn oordosis vermoed word, moet PMX™ dadelik gestaak word.

Behandeling is oor die algemeen simptomaties en ondersteunend.

As jy vergeet om PMX™ te neem
Moenie ʼn dubbele dosis van PMX™ neem om te vergoed vir ʼn individuele dosis wat jy vergeet het nie.

4. Moontlike newe-effekte

PMX™ kan in buitengewone gevalle newe-effekte hê.

Nie alle newe-effekte wat vir PMX™ vermeld is, is in hierdie pamflet ingesluit nie.
As jou algemene gesondheid versleg of as jy enige ongewenste newe-effekte ondervind terwyl jy PMX™ neem, vra asseblief jou gesondheidsdeskundige vir advies.

<u>Minder dikwelse newe-effekte:</u>

- naarheid (voel mislik)
- diarree
- hardlywigheid
- slegte spysvertering
- opgeblaasde maag
- winderigheid

<u>Aanmelding van newe-effekte:</u>
As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, meld dit asseblief by AnaStellar Brands (Edms) Bpk aan by <u>pharmacist@anastellar.co.za</u>, (011) 792 4601 of <u>https://anastellar.co.za</u>.

Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van PMX™ te verskaf.

5.Hoe om PMX™ te bewaar

Hou alle medisyne buite kinders se bereik.
Bewaar teen 25 °C of benede.
Beskerm teen lig en vogtigheid.
Bewaar in die oorspronklike houer.
Moenie ongebruikte medisyne in dreinering- of rioolstelsels (bv. toilette) weggooi nie.

6. Die inhoud van die kartondosie en ander inligting

Wat PMX™ bevat

PMX™ bevat 2 Komponente:

Komponent 1
Elke Pienk Tablet bevat:

Vitamien B6 afgelei van Piridoksaal-5-Fosfaatmonohidraat 54 mg	**50**	**mg**
Vitamien B12 afgelei van Metielkobalamien 50 µg	**50**	**µg**
Vitamien D3 afgelei van Cholekalsiferol 10 mg	**1 000**	**IE**
Biotien	**100**	**µg**
Folaat afgelei van (6S)-5-Metieltetrahidrofolaat 226 µg	**200**	**µg**
Inositol afgelei van Mio-Inositol 100 mg D-Chiro-Inositol 2,5 mg	**102,5**	**mg**
Yster afgelei van Ferrobisglisinaat 25 mg	**5**	**mg**
Magnesium afgelei van Magnesiumoksied 332 mg	**200**	**mg**
Sink afgelei van Sinkoksied 25 mg	**20**	**mg**

Alle minerale word in hul element- en nie-elementvorm weergegee.

Die ander bestanddele is:

<u>Tabletkern</u> - Kalsiumfosfaat-dibasies, Magnesiumstearaat, Povidoon, Silikondioksied, Oplosmiddel 45, Natriumstyselglikolaat

<u>Tabletbedekking</u> - Kastorolie, Flexicoat Pienk, Skellak

Komponent 2
Elke Sagtejel-kapsule bevat:

Nagblomolie *(Oenothera biennis)* 65 – 85% Linoleïensuur 9% Gamma-Linoleïensuur [Saad]	**500**	**mg**
Vitamien E afgelei van d-α-Tokoferolasetaat 200 mg	**200**	**IE**

Die ander bestanddele is Gelatien (Vis oorsprong) en Gliserol.

Hoe PMX™ lyk en die inhoud van die kartondosie

PMX™ bevat ʼn ovaal Pienk Filmbedekte Tablet en ʼn deursigtige-dop ovaal Sagtejel-kapsule gevul met ʼn Geel gekleurde olierige vloeistof.

Elke kartondosie bevat 3 x PVC/PVDC/Aluminium stulpstroke wat elk 10 x tablette per stulpstrook bevat sowel as 3 x PVC/PVDC/Aluminium stulpstroke wat elk 10 x sagtejel-kapsules per stulpstrook bevat. Daar is 6 x stulpstroke binne-in ʼn kartondosie.

Houer van die Registrasiesertifikaat

AnaStellar Brands (Edms) Bpk
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Registrasienommer

Moet toegeken word

Hierdie pamflet is laas in Januarie 2023 hersien

Die Professionele Inligting is beskikbaar by https://anastellar.co.za

Hierdie ongeregistreerde middel is nie deur die SAHPRA vir sy gehalte, veiligheid of beoogde gebruik geëvalueer nie.