

PROFESSIONAL INFORMATION EMOZAC

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

EMOZAC (vegetarian capsules).

COMPOSITION:

Each vegetarian capsule contains:

Active ingredients:	Per capsule
<i>Crocus sativus</i> L. (Safri'Inside™ Saffron stigma extract)	30 mg

Inactive ingredients: Magnesium stearate (vegetable grade) and tapioca starch.

Halaal, sugar free, vegetarian and vegan friendly.

CATEGORY AND CLASS:

Category of medicine: D
Class: D 33.6 Western Herbal
Complementary Medicine.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

EMOZAC contains Safri'Inside™ Saffron stigma extract, which is a product of natural origin, free from dyes, synthetic compounds and adulterations from other species. The crocin component in Saffron helps promote healthy mood and emotional balance. Saffron acts on depressive symptoms through a multi-target mechanism to increase serotonin levels by selective serotonin reuptake inhibition (SSRI), elevate dopamine and glutamate levels and provide neuronal protection through antioxidant activity.

Pharmacokinetic properties:

The active ingredients in this formulation are well known. Pharmacokinetic studies have not been conducted on **EMOZAC**.

INDICATIONS:

EMOZAC assists in the relief of anxiety and depressive symptoms, contributes to emotional balance and promotes a positive mood.

PATIENT INFORMATION LEAFLET

This leaflet tells you about **EMOZAC**.

Complementary Medicine: Western Herbal

SCHEDULING STATUS: **S0**

PROPRIETARY NAME AND DOSAGE FORM:

EMOZAC (vegetarian capsules)

Read all of this leaflet carefully because it contains important information for you. **EMOZAC** is available without a doctor's prescription. Nevertheless, you still need to use **EMOZAC** carefully to get the best results from it. Keep this leaflet. You may need to read it again.
Do not share **EMOZAC** 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 EMOZAC CONTAINS:

Active ingredients:	Per capsule
<i>Crocus sativus</i> L. (Safri'Inside™ Saffron stigma extract)	30 mg

Inactive ingredients: Magnesium stearate (vegetable grade) and tapioca starch.

Halaal, sugar free, vegetarian and vegan friendly.

WHAT EMOZAC IS USED FOR:

EMOZAC assists in the relief of anxiety and depressive symptoms, contributes to emotional balance and promotes a positive mood.

BEFORE YOU TAKE EMOZAC:

Do NOT take EMOZAC:

- If you are allergic to any of the ingredients (see "WHAT EMOZAC CONTAINS").
- If you are pregnant or breastfeeding your baby (see "Pregnancy and breastfeeding").

Take special care with EMOZAC:

Saffron might have a hypotensive effect. Patients on anti-hypertensive medication need to be aware of an increased risk of hypotension.

If you are already taking a prescription anti-depressant, do not start taking **EMOZAC** without first consulting your Doctor. In addition, do not stop your prescribed anti-depressant, or switch to **EMOZAC**, without first seeking professional advice.

EMOZAC does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

Please consult your doctor or pharmacist prior to use if you:

- Have low blood pressure.

Taking EMOZAC capsules with food and drink:

There are no known side effects to taking **EMOZAC** with food and drink. **EMOZAC** is best taken with meals.

Pregnancy and breastfeeding:

Do not use **EMOZAC** during pregnancy or while you are breastfeeding your baby, as safety and efficacy have not been established.

Driving and using machinery:

No studies on the effect on the ability to drive or use machinery have been performed. It is possible that **EMOZAC** would affect your ability to drive or use machinery, as it might cause sedation. Please exercise care until you are certain that your ability to perform such activities is not affected.

Taking other medicines with EMOZAC:

Always tell your healthcare professional if you are taking other medicines on a regular basis, including complementary or traditional medicines. The use of **EMOZAC** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Do not take **EMOZAC** in combination with medicines such as:

- Blood pressure lowering medicines, since concomitant use might increase the risk of hypotension (low blood pressure).
- Barbiturates (for epilepsy), because when used in with Saffron it could increase sedative effects.
- Calcium channel blockers (for high blood pressure and heart conditions), as concomitant use with Saffron may cause additive coronary vasodilatory effects (widening of blood vessels).

CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients (see "COMPOSITION").
- Not recommended during pregnancy and/or lactation.

WARNINGS and SPECIAL PRECAUTIONS:

Saffron might have a hypotensive effect. Patients on anti-hypertensive medication need to be aware of an increased risk of hypotension.

Effects on the ability to drive and use machinery:

No studies on the effect of **EMOZAC** on the ability to drive or operate machinery were performed. It is possible that **EMOZAC** would affect the ability to drive or operate machinery, as it may cause sedation. Please exercise care until you are certain that your ability to perform such activities is not affected.

INTERACTIONS:

Adverse effects have not become known with the simultaneous ingestion of **EMOZAC** and food.

Other interactions known with Saffron extract:

Antihypertensive medicine:

Saffron might decrease blood pressure and concomitant use with antihypertensive medicines such as captopril, enalapril, losartan, valsartan, diltiazem, amlodipine, hydrochlorothiazide and furosemide might cause additive effects and increase the risk of hypotension.

Barbiturate medicine:

Saffron might increase the sedative effects of hexobarbital medicines. The concomitant use of Saffron and barbiturates such as pentobarbital, phenobarbital and secobarbital could have additive sedative effects.

Calcium channel blockers:

The use of Saffron and calcium channel blockers such as verapamil, nifedipine and diltiazem might cause additive coronary vasodilatory effects as Saffron has a negative inotropic and chronotropic activity.

Herbs or supplements:

Theoretically, combining Saffron with other herbs or supplements with hypotensive effects might increase the risk of hypotension.

Herbs and supplements include *Andrographis*, casein peptides, cat's claw, coenzyme Q-10, fish oil, L-arginine, box thorn, stinging nettle and theanine.

- Herbs or supplements with hypotensive effects (blood pressure lowering effects) such as *Andrographis*, casein peptides, cat's claw, coenzyme Q-10, fish oil, L-arginine, box thorn, stinging nettle and theanine, as concomitant use with Saffron might increase the risk of hypotension.

HOW TO TAKE EMOZAC:

The usual dose is:

Adults: Take 1 capsule once daily with a meal.

Do not take more than the recommended daily dose.

If the symptoms worsen or persist, please consult your healthcare practitioner.

If you take more EMOZAC than you should:

If you take more than the recommended dosage for **EMOZAC** in excessive amounts it might cause nausea, vomiting and other gastrointestinal disturbances, yellow appearance of the skin, mucous membranes and sclera, bleeding from the uterus, nose, lips or eyelids, rhinoconjunctivitis and allergy-induced asthma, vertigo, numbness, haematuria or uremic collapse.

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

If you forget to take EMOZAC:

Always take **EMOZAC** as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule (see "HOW TO TAKE EMOZAC"). Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS:

There are no known side effects associated with **EMOZAC**.

Side effects associated with Saffron extract:

Not all side effects reported for Saffron are included in this leaflet. Should your general health worsen while taking **EMOZAC**, please consult your doctor, pharmacist or other healthcare professional for advice.

- Increased or decreased appetite (*frequency unknown*).
- Nausea and vomiting (*frequency unknown*).
- Dry mouth, dyspepsia, diarrhoea and constipation (*less frequent*).
- Sweating and flushing (*frequency unknown*).
- Decreased blood pressure (*frequent*).
- Headache and sedation (*frequency unknown*).
- Allergic reactions (*frequency unknown*).
- Hypomania and anxiety (*frequency unknown*).

Please report/inform your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

STORAGE AND DISPOSING OF EMOZAC:

Store in a cool, dry place at or below 25 °C.

Do not remove the blisters from the original packing until required for use.

Protect from light.

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label. Return all unused **EMOZAC** to your pharmacist.

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

PRESENTATION OF EMOZAC:

EMOZAC: 30 vegetarian capsules are available in PVDC/aluminium blister strips, with each blister containing 10 vegetarian capsules. Each carton contains 3 blister strips.

IDENTIFICATION OF EMOZAC:

A yellow, vegetarian and vegan friendly, hypromellose size 0 capsule with "EMOZAC" printed on the capsule body.

REGISTRATION NUMBER:

To be allocated.

EMOZAC is an unregistered medicine and has not been evaluated by the SAHPRA for its quality, safety or intended use.

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

RELEAF PHARMACEUTICALS (PTY) LTD
14 De Vreugde Crescent
Dal Josaphat
Paarl
7646
Tel: +27 (21) 001 9748
Email: info@releafpharma.co.za

RP1214/19A
06/2019
BRITEPAK

DATE OF PUBLICATION: June 2019.

HUMAN REPRODUCTION:

Pregnancy and lactation:

Not recommended for use during pregnancy or lactation, as the safety and efficacy have not been established.

DO dosage AND DIRECTIONS FOR USE:

Adults: Take 1 capsule once daily with a meal.

SIDE EFFECTS:

Gastrointestinal disorders:

Frequency unknown: Increased or decreased appetite, nausea and vomiting.

Less frequent: Dry mouth, dyspepsia, diarrhoea and constipation.

Dermatologic disorders:

Frequency unknown: Sweating and flushing.

Vascular disorders:

Frequent: Decreased blood pressure.

Nervous system disorders:

Frequency unknown: Headache and sedation.

Immune system disorders:

Frequency unknown: Allergic reactions.

Psychiatric disorders:

Frequency unknown: Hypomania and anxiety.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Excessive intake of 5 g or more might lead to Saffron poisoning. Symptoms include yellow appearance of the skin, mucous membranes and sclera, vomiting, bloody diarrhoea, bleeding from the uterus, nose, lips and eyelids, rhinconjunctivitis and allergy-induced asthma, vertigo and numbness, haematuria or uremic collapse. Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

A yellow, vegetarian and vegan friendly hypromellose size 0 capsule with "EMOZAC" printed on the capsule body.

PRESENTATION:

EMOZAC: 30 vegetarian capsules are available in PVDC/aluminium blister strips, with each blister containing 10 vegetarian capsules. Each carton contains 3 blister strips.

RP1214/19A
06/2019
BRITEPAK

PASİENTINLIGTINGSBLAD Inligting oor EMOZAC.

Komplementêre Medisyne: Westerse Kruie

SKEDULERINGSSTATUS: **S0**

EIENDOMSNAAM EN DOSEERVORM:

EMOZAC (vegetariese kapsules).

Lees die hiele inligtingsblad deeglik, want dit bevat belangrike inligting. **EMOZAC** is beskikbaar sonder 'n dokter se voorskryf. U moet egter steeds **EMOZAC** versigtig gebruik om die beste resultate daarmee te verkry. Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees. Moenie **EMOZAC** met enige ander persoon deel nie. Indien u verdere inligting of advies verlang, vra asseblief u apteker. U moet 'n dokter raadpleeg indien u simptome vererger.

WAT EMOZAC BEVAT:

Elke kapsule bevat:

Aktiewe bestanddele: Per kapsule
Crocus sativus L. (Saf'r'Inside™ Saffraan stempel ekstrak) 30 mg

Onaktiewe bestanddele: Magnesiumstearaat (plante afkoms) en tapiokastysel.

Halaa!, suikervry, vegetaries en veganies vriendelik.

WAARVOOR EMOZAC GEBRUIK WORD:

EMOZAC ondersteun met die verligting van angs en depressiewe simptome, dra by tot emosionele balans en bevorder 'n positiewe gemoedstoestand.

VOOR U EMOZAC NEEM:

Moet NIE EMOZAC gebruik NIE:

- Indien u allergies is vir enige van die bestanddele (sien "WAT EMOZAC BEVAT").
- Indien u swanger is of u baba borsvoed (sien "Swangerskap en borsvoeding").

Neem spesiale sorg met EMOZAC:

Pasiënte met lae bloeddruk moet bewus wees van 'n moontlike verlaging in bloeddruk wanneer Saffraan gebruik word.

Indien u reeds voorgeskrewe anti-depressante gebruik, moet nie **EMOZAC** neem sonder om u dokter te raadpleeg nie. Moet ook nie u voorgeskrewe anti-depressante stop en met **EMOZAC** begin sonder advies van u dokter nie.

EMOZAC beoog nie om enige ongesteldheid of siektetoestand te genees nie en moet nie enige medikasie vervang nie. Mensse wat aan 'n chroniese mediese toestand ly moet hulle gesondheidspraktisyn raadpleeg vir hulle hierdie produk gebruik.

Raadpleeg asseblief u dokter of apteker voor gerbuik indien u:

- Aan lae bloeddruk lei.

EMOZAC met kos en drinkgoed:

Daar is geen bekende newe-effekte om **EMOZAC** saam met kos en drinkgoed te neem nie. **EMOZAC** moet verkieslik saam met voedsel geneem word.

Swangerskap en borsvoeding:

Moenie **EMOZAC** neem terwyl u swanger is of u baba borsvoed nie, aangesien die veiligheid hiervan nie bepaal is nie.

Bestuur en die gebruik van masjinerie:

Geen navorsingsstudies is uitgevoer oor die effek op die vermoë om te bestuur of masjinerie te hanter nie. Dit is moontlik dat **EMOZAC** die vermoë om te bestuur of masjinerie te gebruik sal beïnvloed, deur dat dit sedasie kan veroorsaak. Wees egter versigtig tot u seker is u vermoë om hierdie aktiwiteite uit te voer word nie beïnvloed nie.

Die neem van ander medisyne saam met EMOZAC:

Lig altyd u gesondheidspraktisyn in wanneer u medisyne op 'n gereelde grondslag neem, insluitend komplementêre of tradisionele medisyne. Die gebruik van **EMOZAC** saam met hierdie medisyne mag ongewenste wisselwerkings veroorsaak. Raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker.

Moenie **EMOZAC** in kombinasie met medisyne soos die volgende gebruik nie:

- Bloeddruk verlagende medikasie (antihypertensiewe middels) aangesien die gepaardgaande gebruik met Saffraan lae bloeddruk mag veroorsaak.
- Barbituraat medikasie (vir epilepsie ens.), want Saffraan kan die sederende effek vererger.
- Kalsium kanaal blokkeerders (vir hoë bloeddruk en hartkwaal), aangesien Saffraan koronêre bloedsaak verbreding kan veroorsaak.
- Kruie en aanvullings met hipotensiewe eienskappe (bloeddruk verlagende effekte) onder andere *Andrographis*, kaseien peptiede,

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.

Do not remove the blisters from the original packing until required for use.

Do not use after expiry date.

Keep the container tightly closed.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

EMOZAC is an unregistered medicine and has not been evaluated by SAHPRA for its quality, safety or intended use. **EMOZAC** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product. Do not exceed the recommended dose.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

RELEAF PHARMACEUTICALS (PTY) LTD

14 De Vreugde Crescent

Dal Josaphat

Paarl

7646

Tel: +27 (21) 001 9748

Email: info@releafpharma.co.za

DATE OF PUBLICATION: June 2019.

katteklouranker, ko-ensiem Q-10, vis olie, L-arginien, bokdoring, brandnetel en teanian, want die gesamentlike inname met Saffraan mag lae bloeddruk veroorsaak.

HOE OM EMOZAC TE GEBRUIK:

Die normale dosis is:

Volwassenes: Neem 1 kapsule een keer per dag met 'n maaltyd.

Moenie die voorgeskrewe dosis oorskry nie.

As die simptome vererger of voortduur, raadpleeg 'n gesondheidsorgpraktisyn.

Indien u meer EMOZAC geneem het as wat u moes:

Indien u meer **EMOZAC** geneem het as wat u moes, in 'n buitensporige hoeveelheid, kan u moontlik naarheid, braking en ander dermkanale-erwante simptome, 'n geel voorkoms van die vel, mukusmembran en sklera, bloeding van die uterus, neus, lippe en oogiede, rhinokonjunktivitis en allergie-geïnduseerde asma, duisligheid, gevoelloosheid, hematurie (bloed in uriene) of uremiese ineenstorting ervaar.

Indien u Saffraan vergifting opdoen, skakel u dokter of gesondheidspraktisyn so gou moontlik. Indien niemand beskikbaar is nie, kontak u naaste hospitaal of gifbeheersentrum.

Indien u vergeet om EMOZAC te neem:

Neem **EMOZAC** altyd soos voorgeskryf. Indien u 'n dosis vergeet het, neem dit sou gou as wat u onthou. Indien u egter nie van die vergete dosis onthou voordat dit tyd is vir die volgende dosis is nie, slaan die vergete dosis oor en keer terug na u gewone doseringskedule (sien "HOE OM EMOZAC TE GEBRUIK"). Moenie 'n dubbele dosis neem om te vergoed vir die oorgeslane individuele dosis nie.

MOONTLIKE NEWE-EFFEKTE:

Daar is geen bekende newe-effekte wat gepaard gaan met **EMOZAC** nie.

Newe-effekte geassosieer met Saffraan ekstrak:

Nie alle newe-effekte wat vir Saffraan ekstrak gemeld is, is in hierdie inligtingstuk vervat nie. Indien u algemene gesondheid agteruitgaan terwyl u **EMOZAC** gebruik, raadpleeg asseblief u dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

- Verhoogde of verlaagde eetlus (*frekwensie onbekend*).
- Naarheid en braking (*frekwensie onbekend*).
- Droë mond, dispensie, diarree en hardlywigheid (*minder algemeen*).
- Sweet en bloosheid (*frekwensie onbekend*).
- Verlaging van bloeddruk (*algemeen*).
- Hoofpyn en sedasie (*frekwensie onbekend*).
- Allergiese reaksies (*frekwensie onbekend*).
- Hipomanie en angstigtheid (*frekwensie onbekend*).

Lig asseblief u dokter of apteker in indien u enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

BERGING EN WEGDOEN VAN EMOZAC:

Bewaar in 'n koel, droë plek by of benede 25 °C. Moenie die stolverpakkings uit die oorspronklike verpakking verwyder totdat dit nodig is vir gebruik nie.

Beskerm teen lig.

HOU ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.

Moenie gebruik na die vervaldatum op die etiket nie. Neem alle ongebruikte **EMOZAC** na u apteker terug.

Moenie ongebruikte **EMOZAC** in afvoerpype of rioolsisteme (byvoorbeeld toilette) weggooi nie.

AANBIEDING VAN EMOZAC:

EMOZAC: 30 vegetariese kapsules is verpak in PVDC/aluminium stolverpakkings, met elke stolverpakkings wat 10 vegetariese kapsules bevat. Elke dosie bevat 3 stolverpakkings.

IDENTIFIKASIE VAN EMOZAC:

'n Geel, vegetaries en veganies vriendelike hypromellose grootte 0 kapsule, met "EMOZAC" gedruk op die kapsuulliggaam.

REGISTRASIONOMMER:

Sal toegeken word.

EMOZAC is nie geregistreer nie en nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

NAAM EN SAKAADRES VAN DIE HOUER VAN DIE REGISTRASIE:

RELEAF PHARMACEUTICALS (EDMS) BPK

De Vreugde Singel 14

Dal Josaphat

Paarl

7646

Tel: +27 (21) 001 9748

E-pos: info@releafpharma.co.za

RP1214/19A
06/2019
BRITEPAK

DATUM VAN PUBLIKASIE: Junie 2019.