Front Top
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EMERDYNE
10 / 20 mg
PM03914302

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

EMERDYNE 10 mg (film-coated tablets)
Escitalopram oxalate corresponding to 10 mg Escitalopram
Contains sugar (104.33 of lactose monohydrate).

EMERDYNE 20 mg (film-coated tablets)
Escitalopram oxalate corresponding to 20 mg Escitalopram
Contains sugar (208.67 mg of lactose monohydrate).

Read all of this leaflet carefully before you start taking EMERDYNE
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **EMERDYNE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What EMERDYNE is and what it is used for

The treatment of major depressive disorders.

2. What you need to know before you take EMERDYNE

Do not take EMERDYNE if:
1. If you are hypersensitive (allergic) to escitalopram or to any of the other ingredients of **EMERDYNE.**
2. If you are under the age of 18 years.
3. If you are born with or have had an episode of abnormal heart rhythm (seen on ECG; an examination to evaluate how the heart is functioning).
4. If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see "**Other medicines and EMERDYNE**").
5. If you take other medicines that belong to a group called MAO inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide and tranylcypromine (used in the treatment of depression). Do not start **EMERDYNE** if you stopped taking an MAOI in the last 2 weeks. Do not take an MAOI within 1 week of stopping **EMERDYNE**.

Warnings and precautions
Talk to your doctor or pharmacist before taking **EMERDYNE**
Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:
- If you have coronary heart disease.
- If you suffer or have suffered from heart problems or have recently had a heart attack.
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting or usage of diuretics (water tablets).
- If you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.
- If you have diabetes. Treatment with **EMERDYNE** may alter blood sugar control. Insulin and/or oral hypoglycaemic medicine dosage may need to be adjusted.
- If you have epilepsy. Treatment with **EMERDYNE** should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency.
- If you have a tendency to easily develop bleedings or bruises or if you are taking medicines that affect the blood clotting function e.g. aspirin, non-steroidal anti-inflammatory medicines (NSAIDs), tricyclic antidepressants and other medicines you may be taking to treat mental illness.
- If you are receiving electroconvulsive treatment for mental illness.
- If you suffer from impaired liver function. Your doctor may need to adjust your dosage.
- Some patients with manic-depressive illness may enter into a manic phase. This is characterised by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor. Symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.
- Thoughts of suicide and worsening of your depression or anxiety disorder. If you are depressed and/or have anxiety disorders you can sometimes experience increased anxiety symptoms or have thoughts of harming or killing yourselves. These may be increased when first starting antidepressants, including **EMERDYNE**, since these medicines all take time to work, usually about two weeks but sometimes longer. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.
- There has been a relation between a group of medicine called SSRI and SNRI and heavy bleeding following birth. **EMERDYNE** belongs to the group of medicines called SSRIs. If you have any bleeding disorders or are pregnant, your doctor will have to change your treatment to an alternative group of medicines.

Other medicines and EMERDYNE
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Inform your doctor if you are taking any of the following medicines:
- Monoamine oxidase inhibitors (medicines used for depression and anxiety)
- Sumatriptan (used to treat migraine)
- Tramadol (used for severe pain)
- Lithium or tryptophan (used for treatment of mental illness with depression)
- Cimetidine (used for treating stomach ulcers)
- Desipramine (used to treat depression)
- Metoprolol (beta-blocker used to treat angina (chest pain) and high blood pressure)
- Selegiline (used to treat Parkinson's disease)
- Warfarin (medicine used to thin the blood)

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

EMERDYNE with food and drink:
EMERDYNE may be taken with or without food in the morning or evening.

Pregnancy, breastfeeding and fertility
Safety in pregnancy and breast-feeding has not been established.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking **EMERDYNE.**

Driving and using machines
Patients who are depressed and require treatment may have an impaired ability to drive or operate machinery. Furthermore, **EMERDYNE** can induce fatigue, dizziness, drowsiness and impair vision. Your doctor will routinely evaluate your ability to continue driving or operating complex machines while taking **EMERDYNE**.

Important information about some of the ingredients of EMERDYNE
Tell your doctor if you have galactosaemia (a condition in which the body is unable to use the sugar galactose) or glucose / galactose malabsorption syndrome (a condition in which lactose (milk sugar) and other carbohydrates, which contain the sugars glucose and galactose, cannot be digested by the body). **EMERDYNE** contains lactose (milk sugar) and is unsuitable for patients with these disorders.
Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

3. How to take EMERDYNE

Do not share medicines prescribed for you with any other person.
Always take **EMERDYNE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take **EMERDYNE** by mouth.

The usual dose is:
Major Depressive disorders
10 mg a day as a single dose. Your doctor may increase your dose to a maximum of 20 mg daily, depending on your response to treatment.
Usually 2-4 weeks are necessary to obtain antidepressant response.
Elderly: (> 65 years of age)
Your doctor may recommend a lower starting dose.

Reduced hepatic (liver) function:
Your doctor may recommend 5 mg a day as a single dose for the first two weeks of treatment, dependent on your response to treatment, the dose may be increased to 10 mg, a day.
If you have the impression that the effect of **EMERDYNE** is too strong or too weak, talk to your doctor or pharmacist.

If you take more EMERDYNE than you should
You may experience the following symptoms:
Dizziness, tremor, agitation, sleepiness, unconsciousness, seizures, increased or irregular heartbeat, respiratory depression, vomiting, rhabdomyolosis (destruction of muscle cells), metabolic acidosis and hypokalaemia (low potassium in the blood).
In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take EMERDYNE:
Do not take a double dose to make up for forgotten individual doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

If you stop taking EMERDYNE:
Your doctor will tell you how long your treatment with **EMERDYNE** will last. **EMERDYNE** should be gradually withdrawn over a couple of weeks when stopping therapy.

4. Possible side effects

EMERDYNE can have side effects.
Not all side effects reported for EMERDYNE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking EMERDYNE and tell your doctor immediately or go to the casualty department at your nearest hospital.
These are serious side effects and you may need urgent medical attention:
- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), contact your doctor or go to a hospital straight away.
- If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.
- Difficulties urinating.
- Seizures (fits).
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis.
- Fast, irregular heartbeat and fainting which could be symptoms of a life-threatening condition known as torsade de pointes.

Tell your doctor promptly about these or any other unusual symptoms. If the symptoms persist or worsen, seek medical attention.
- Unusual bleeds, including gastrointestinal bleeds.
- Thoughts of harming yourself or thoughts of killing yourself.

Check with your doctor if any of the following side effects worry you:
Frequent side effects may include:
- Decreased appetite, weight loss
- Anxiety, feeling restless, abnormal dreams, decreased libido and women may experience difficulties achieving orgasm
- Difficulties falling asleep, feeling sleepy, dizziness, drowsiness
- Blocked or runny nose (sinusitis), yawning
- Nausea, vomiting, dry mouth, diarrhoea, constipation, taste disturbances, eating disorders (anorexia), upset stomach
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, impotence and decreased sexual drive)
- Fatigue, fever

Less frequent side effects
- Swelling of the arms or legs, allergic reaction
- Decreased weight
- Disturbance in taste, feeling sleepy, fainting, serotonin syndrome characterised by agitation, confusion, increased heart rate, high blood pressure, twitching muscles, dilated pupils, heavy sweating and muscle rigidity
- Abnormal vision
- Ringing in the ears (tinnitus)
- Fast or slow heartbeat
- Nose bleeds
- Bleeding in the gut, including rectal bleeding
- Rash, itching, sweating, hair loss, photosensitivity
- Women: abnormal bleeding
- Flow of milk in women that are not breast-feeding
- Swelling of the arms and legs

Frequency unknown
- A condition characterized by abnormally low levels of platelets in the blood (thrombocytopenia)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confusion)
- Suicidal behaviour or have suicidal thoughts, mania characterised by increased activity, energy or agitation, exaggerated sense of well-being and self-confidence, decreased need for sleep, unusual talkativeness and racing thoughts
- seizures (fits), tremors, movement disorders (involuntary movements of the muscles)
- Anxiety, agitation, nervousness, panic attack, confusion, mentally ill (aggression, depersonalisation, hallucination)
- Akathisia (a feeling of muscle quivering, restlessness and inability to sit still, sometimes a side effect of antipsychotic or antidepressant medication.)
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, measuring electrical activity of the heart)
- Dizziness when you stand up due to low blood pressure
- Abnormal liver function tests (increased amounts of liver enzymes in the blood) and swelling of the liver
- Bruising
- Difficulty in emptying the bladder
- Male: priapism (unwanted, persistent erection), female: flow of milk in women that are not breast-feeding
- Haemorrhage (heavy bleeding) after giving birth

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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf By reporting side effects, you can help provide more information on the safety of **EMERDYNE.**

5. How to store EMERDYNE

Store at or below 25 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Keep the HDPE container tightly closed.
Store in the original package in order to protect from light and moisture.

KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / 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 pack and other information

What EMERDYNE contains

EMERDYNE 10 mg (film-coated tablets)
Each film-coated tablet contains:
Escitalopram oxalate corresponding to 10 mg.

EMERDYNE 20 mg (film-coated tablets)
Each film-coated tablet contains:
Escitalopram oxalate corresponding to 20 mg.

Other ingredients include:
Croscarmellose sodium, isopropyl alcohol, lactose monohydrate, magnesium stearate, propyl gallate, sodium carboxymethylcellulose, colloidal silicon dioxide, hydroxypropylmethylcellulose, titanium dioxide (E171), polyethylene glycol.

What EMERDYNE looks like and contents of the pack
EMERDYNE 10 mg (film-coated tablets)
A white to off white, circular, biconvex, film coated tablet having "ML 60" debossed on one side, break line on opposite side and having notches on either ends of break line.

EMERDYNE 20 mg (film-coated tablets)
A white to off white, circular, biconvex, film coated tablet having "ML 61" debossed on one side, break line on opposite side and having notches on either ends of break line.

Blister pack (30's)
Tablets are packed in cold form laminate, 25 µm OPA/45 µm Aluminum foil/60 µm PVC as the forming material and plain 25 micron, aluminum foil, 6-8 gsm HSL, as the lidding material.
Aluminium blister pack of 3 x 10 (30) tablets. The blisters are placed in an outer carton.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in
11 April 2021

Registration number
EMERDYNE 10 mg: 45/1.2/0881
EMERDYNE 20 mg: 45/1.2/0882

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

Back Top
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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

EMERDYNE 10 mg (filmbedekte tablette)
Essitalopramoksalaat gelykstaande aan 10 mg Essitalopram
Bevat suiker (104,33 mg laktosemonohidraat).

EMERDYNE 20 mg (filmbedekte tablette)
Essitalopramoksalaat gelykstaande aan 20 mg Essitalopram
Bevat suiker (208,67 mg laktosemonohidraat).

Lees hierdie hele inligtingsblad sorgvuldig deur, voordat jy begin om EMERDYNE te gebruik
- Hou hierdie inligtingsblad. Dit mag wees dat jy dit weer wil lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer, indien jy verdere vrae het.
- **EMERDYNE** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik wees vir hulle, selfs al is hulle simptome dieselfde as joune.

Wat in hierdie inligtingsblad is

1. Wat **EMERDYNE** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **EMERDYNE** neem
3. Hoe om **EMERDYNE** te neem
4. Moontlike newe-effekte
5. Hoe om **EMERDYNE** te berg
6. Inhoud van die pak en ander inligting

1. Wat EMERDYNE is en waarvoor dit gebruik word

Die behandeling van erge depressieversteurings.

2. Wat jy behoort te weet voordat jy EMERDYNE gebruik

Moet nie EMERDYNE gebruik nie:
1. Indien jy hipersensitief (allergies) is vir essitalopram, of enige van die ander bestanddele van **EMERDYNE**.
2. Indien jy jonger as 18 jaar oud is.
3. Indien jy gebore is met, of 'n episode van abnormale hartritme gehad het (soos gesien op 'n EKG; 'n ondersoek om te evalueer hoe die hart funksioneer).
4. Indien jy medisyne neem vir probleme met hartritme of wat die hartritme kan beïnvloed (sien "**Ander medisyne en EMERDYNE**").
5. As jy ander medisyne neem wat behoort aan 'n groep genaamd MAO-inhibeerders, insluitend selegilien (wat gebruik word in die behandeling van Parkinson se siekte), moklobemied en tranielsipromien (gebruik in die behandeling van depressie). Moet nie **EMERDYNE** begin gebruik indien jy gedurende die afgelope 2 weke opgehou het om 'n MAOI te neem nie. Moet nie 'n MAOI neem binne 1-week nadat **EMERDYNE** gestaak is nie.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy **EMERDYNE** begin gebruik.
Vertel asseblief jou dokter as jy enige ander toestand of siekte het, aangesien jou dokter dit moontlik in ag moet neem. Vertel jou dokter in die besonder:
- As jy 'n koronêre hartsiekte het.
- Indien jy aan hartprobleme ly of gely het, of onlangs 'n hartaanval gehad het.
- As jy 'n lae rustende harttempo het en/of jy weet dat jy moontlik sout-uitputting het as gevolg van langdurige ernstige diarree en braking of die gebruik van diuretika (watertablette).
- Indien jy 'n vinnige of onreëlmatige hartklop, floute, ineenstorting of duiseligheid ervaar wanneer jy opstaan, wat kan dui op 'n abnormale funksionering van die harttempo.
- As jy diabetes het. Behandeling met **EMERDYNE** kan die beheer van bloedsuiker verander. Die dosis van insulien en/of mondelinge hipoglukemiese medisyne sal moontlik aangepas moet word.
- Indien jy epilepsie het. Behandeling met **EMERDYNE** moet gestaak word as aanvalle vir die eerste keer voorkom, of as daar 'n toename in die frekwensie van aanvalle is.
- As jy geneig is om maklik bloedings of kneusplekke op te doen, of as jy medisyne gebruik wat die bloedstollingsfunksie beïnvloed, bv. aspirien, nie-steroïed anti-inflammatoriese middels (NSAIMs), trisikliese antidepressante en ander medisyne wat jy moontlik mag gebruik om geestesgesondheidsprobleme te behandel.
- Indien jy elektrokonvulsiewe behandeling ontvang vir die behandeling van geestesgesondheidsprobleme.
- As jy aan 'n ingekorte lewerfunksie ly. Dit mag moontlik nodig wees vir jou dokter om jou dosis aan te pas.
- Sommige pasiënte met 'n maniese-depressiewe siekte kan in 'n maniese fase ingaan. Dit word gekenmerk deur ongewone en vinnig veranderende idees, onvanpaste gelukkigheid en oormatige fisiese aktiwiteit. Kontak jou dokter indien jy dit ervaar. Simptome soos rusteloosheid of probleme met sit of stilstaan kan ook gedurende die eerste weke van die behandeling voorkom. Vertel onmiddellik jou dokter indien jy hierdie simptome ervaar.
- Gedagtes van selfmoord en verergering van jou depressie of angsversteuring. As jy depressief is en/of 'n angsversteuring het, kan jy soms verhoogde angssimptome ervaar of jy kan selfmoordgedagtes of idees ontwikkel om jouself te beseer. Hierdie kan verhoog word wanneer jy vir die eerste keer antidepressante begin gebruik, insluitend **EMERDYNE**, aangesien hierdie middels almal tyd neem om te werk, gewoonlik ongeveer twee weke, maar soms langer. As jy op enige tydstip idees ontwikkel om jouself te beseer, of selfmoordgedagtes het, kontak jou dokter of gaan onmiddellik na 'n hospitaal.
- Daar bestaan 'n verband tussen 'n groep medisyne bekend as SSHI en SNHI en swaar bloeding na geboorte. **EMERDYNE** behoort tot die groep medisyne wat SSHI's genoem word. Indien jy enige bloedingsversteurings het of swanger is, sal jou dokter jou behandeling moet verander na 'n alternatiewe groep van medisyne.

Ander medisyne en EMERDYNE
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Stel jou dokter in kennis indien jy een van die volgende medisyne gebruik:
- Monoamienoksidase-inhibeerders (medisyne wat gebruik word vir depressie en angs)
- Sumatriptaan (gebruik om skeelhoofpyn(migraine) te behandel)
- Tramadol (gebruik vir erge pyn)
- Litium of triptofaan (gebruik om geestesgesondheidsprobleme met depressie te behandel)
- Simetidien (gebruik om maag ulkusse te behandel)
- Desipramien (gebruik om depressie te behandel)
- Metoprolol (beta-blokkers wat gebruik word om angina (borskaspyn) en hoë bloeddruk te behandel)
- Selegilien (gebruik om Parkinson se siekte te behandel)
- Warfarien (medisyne wat gebruik word om die bloed te verdun)

Vertel altyd jou gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

EMERDYNE met voedsel en drinkgoed:
EMERDYNE kan met of sonder voedsel geneem word in die oggend of in die aand

Swangerskap, borsvoeding en fertiliteit
Die veiligheid in swangerskap en borsvoeding is nog nie vasgestel nie.
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgwerker vir advies voordat jy **EMERDYNE** begin gebruik.

Bestuur en gebruik van masjinerie
Pasiënte wat depressief is en wat behandeling benodig, se vermoë om te bestuur of om masjienerie te hanteer, kan ingekort wees. Verder kan **EMERDYNE** moegheid, duiseligheid, slaperigheid en belemmerde sig veroorsaak. Jou dokter sal gereeld jou vermoë, om aan te hou bestuur of om ingewikkelde masjinerie te hanteer, evalueer, terwyl jy **EMERDYNE** gebruik.

Belangrike inligting oor sommige van die bestanddele van EMERDYNE
Vertel jou dokter as jy galaktosemie het ('n toestand waarin die liggaam nie in staat is om die suiker, galaktose, te kan gebruik nie) of glukose/galaktose wanabsorpsie sindroom ('n toestand waarin laktose (melksuiker) en ander koölhidrate wat glukose- en galaktose suikers bevat, nie deur die liggaam verteer kan word nie). **EMERDYNE** bevat laktose (melksuiker) en is nie geskik vir pasiënte met hierdie afwykings nie.
Bespreek dit met jou dokter, verpleegkundige of apteker indien jy onseker is oor enige iets.

3. Hoe om EMERDYNE te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **EMERDYNE** presies soos jou dokter dit vir jou voorgeskryf het. Vra jou dokter of apteker, indien jy onseker is.
Neem **EMERDYNE** per mond in.

Die aanbevole dosis is:
Erge depressieweversteurings
10 mg per dag as 'n enkel dosis. Jou dokter kan jou dosis verhoog tot 'n maksimum van 20 mg per dag, afhangende van jou reaksie op die behandeling.
'n Periode van 2 - 4 weke is gewoonlik nodig om 'n antidepressante resaksie te verkry.

Bejaarde pasiënte: (> 65 jaar oud)
Jou dokter kan 'n laer aanvangsdosering aanbeveel.

Ingekorte hepatiese (lewer) funksie:
Jou dokter kan 5 mg per dag as 'n enkel dosis aanbeveel vir die eerste twee weke van behandeling, afhangende van jou reaksie op die behandeling, kan die dosis verhoog word tot 10 mg per dag.
Indien jy onder die indruk is dat die effek van **EMERDYNE** te sterk of te swak is, praat dan met jou dokter of apteker.

Indien jy meer EMERDYNE neem as wat jy behoort te neem
Jy kan die volgende simptome ervaar:
Duiseligheid, bewing, rusteloosheid, slaperigheid, bewusteloosheid, aanvalle, verhoogde of onreëlmatige hartklop, respiratoriese onderdrukking, braking, rabdomiolose (vernietiging van spierselle), metaboliese asidose en hipokalemie (lae kaliumbloedvlakke).
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om EMERDYNE te neem:
Moet nie 'n dubbele dosis neem om vir die vergete individuele dosisse op te maak nie. Indien jy vergeet om 'n dosis te neem en jy onthou daarvan voordat jy bed toe gaan om te gaan slaap, neem dit dan dadelik. Gaan voort soos gewoonlik die volgende dag. As jy eers gedurende die nag of die volgende dag daarvan onthou, moet jy die dosis wat jy oorgeslaan het uitlaat en voortgaan soos gewoonlik.

As jy ophou om EMERDYNE te neem:
Jou dokter sal jou vertel hoe lank jou behandeling met **EMERDYNE** sal duur. **EMERDYNE** moet geleidelik oor 'n paar weke onttrek word wanneer die behandeling gestaak word.

4. Moontlike newe-effekte

EMERDYNE kan newe-effekte hê.
Nie alle newe-effkete gerapporteer vir EMERDYNE, word in die inligtingblad ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl jy hierdie medisyne neem, kontak asseblief jou dokter, apteker of gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om EMERDYNE te gebruik en vertel jou dokter onmiddellik of gaan dadelik na die ongevalle afdeling van jou naaste hospitaal:
Hierdie is ernstige newe-effekte en jy benodig moontlik dringende mediese hulp:
- As jy swelling van jou vel, tong, lippe of gesig ervaar, of moeilik asemhaal of sluk (allergiese reaksie), kontak jou dokter of gaan dadelik na 'n hospitaal.
- As jy 'n hoë koors, rusteloosheid (agitasie), verwarring, bewing en skielike sametrekkings van jou spiere het, kan dit tekens wees van 'n seldsame toestand wat serotoniensindroom genoem word.
- Probleme met urinering.
- Aanvalle (stuiptrekkings).
- Wanneer jou vel en die wit van jou oë geel word, is dit tekens van inkorting van die lewerfunksie/hepatitis.
- Vinnige, onreëlmatige hartklop, floute wat simptome kan wees van 'n lewensbedreigende toestand wat bekend staan as *Torsade de Pointes*.

Lig jou dokter onmiddellik in oor hierdie, of enige ander ongewone simptome. As die simptome voortduur of vererger, soek mediese hulp.
- Ongewone bloeding, insluitend gastroïntestinale bloeding.
- Gedagtes om jouself te beseer of gedagtes om jouself dood te maak.

Raadpleeg jou dokter indien jy bekommerd is oor enige van die volgende newe-effekte:
Gereelde newe-effekte kan insluit:
- Verminderde eetlus, gewigsverlies
- Angstigheid, gevoel van rustelоosheid, abnormale drome, verminderde libido en vroue kan probleme ondervind om orgasme te kry
- Probleme om aan die slaap te raak, voel slaperig, duiseligheid, lomerigheid
- Geblokkeerde, of loopneus (sinusitis), gaap
- Naarheid, braking, droë mond, diarree, hardlywigheid, veranderinge in smaak, eetversteurings (anoreksie), omgekrapte maag
- Verhoogde sweet afskeiding
- Pyn in spiere en gewrigte (artralgie en mialgie)
- Seksuele versteurings (vertraagde ejakulasie, probleme met ereksie, impotensie en verminderde seksuele drang)
- Moegheid, koors

Minder gereelde newe-effekte
- Swelling van die arms of bene, allergiese reaksie
- Gewigsverlies
- Verandering in smaak, voel slaperig, floute, serotoniensindroom wat gekenmerk word deur agitasie, verwarring, verhoogde harttempo, hoë bloeddruk, spiertrekkings, gedilateerde pupille, erge sweet en spierstyfheid
- Abnormale visie
- Suising in die ore (tinnitus)
- Vinnige of stadige hartklop
- Neusbloeding
- Bloeding in die ingewande, insluitend rektale bloeding
- Veluitslag, jeuk, sweet, haarverlies, ligsensitiwiteit
- Vroue: abnormale bloeding
- Melk wat vloei by vroue wat nie borsvoed nie
- Swelling van die arms en bene

Frekwensie onbekend
- 'n Toestand wat gekenmerk word deur abnormale lae vlakke van bloedplaatjies in die bloed (trombositopenie)
- Toename in die hoeveelheid uriene wat uitgeskei word (onvanpaste ADH-afskeiding)
- Verlaagde bloednatriumvlakke (die simptome sluit in: voel siek en sleg met swak spiere of verwardheid)
- Selfmoordgedrag of selfmoordgedagtes, manie wat gekenmerk word deur verhoogde aktiwiteit, energie of agitasie (rusteloosheid), oordrewe gevoel van welsyn en selfvertroue, verminderde behoefte aan slaap, praat ongewoon baie en dwalende gedagtes
- Aanvalle (stuiptrekkings), bewing, bewegingsversteurings (onwillekeurige bewegings van die spiere)
- Ang, agitasie, senuweeagtigheid, paniekaanvalle, verwarring, geestesongesteldheid (aggressie, depersonalisasie, hallusinasie)
- Akatisie ('n gevoel van bibberende spiere, rusteloosheid en onvermoë om stil te sit, soms 'n newe-effek van antipsigotiese of antidepressante medikasie.)
- Verandering van die hartritme (genoem "verlenging van QT-interval", gesien op EKG, wat die elektriese aktiwiteit van die hart meet)
- Gevoel van duiseligheid wanneer jy opstaan, as gevolg van lae bloeddruk
- Abnormale lewerfunksietoetse (verhoogde hoeveelhede lewerensieme in die bloed) en swelling van die lewer
- Kneusing
- Probleme met die leegmaak van die blaas
- Mans: priapisme (ongewenste, aanhoudende ereksie), vroue: melk wat vloei by vroue wat nie borsvoed nie
- Hemoragie (swaar bloeding) nadat geboorte geskenk is

As jy enige newe-effekte ervaar wat nie in hierdie inligtingstuk genoem word nie, moet jy jou dokter of apteker daarvan in kennis stel.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsblad genoem is nie. Jy kan ook newe-effekte aanmeld by SAHPRA via die "**6.04 Adverse Drug Reaction & Quality Problem Reporting Form**", wat aanlyn gevind kan word onder SAHPRA se publikasies:https:// sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan_2020.pdf. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **EMERDYNE** te voorsien.

5. Hoe om EMERDYNE te berg

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig.
Hou die stulpstroke in die karton, totdat dit benodig word vir gebruik.
Hou die HDPE houer dig gesluit.
Stoor in die oorspronklike houer om teen lig en vog te beskerm.
BEWAAR BUITE BEREIK VAN KINDERS.
Moet nie in die badkamer stoor nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstroke/etiket/karton/bottel gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die riool of rioolstelsel (bv. toilet) gooi nie.

6. Inhoud van die pak en ander inligting

Wat EMERDYNE bevat

EMERDYNE 10 mg (filmbedekte tablette)
Elke filmbedekte tablet bevat:
Essitalopramoksalaat gelykstaande aan 10 mg essitalopram.

EMERDYNE 20 mg (filmbedekte tablette)
Elke filmbedekte tablet bevat:
Essitalopramoksalaat gelykstaande aan 20 mg essitalopram.

Ander bestanddele sluit in: Natriumkruiskarmellose, isopropielalkohol, laktosemonohidraat, magnesiumstearaat, propielgallaat, natriumkarboksimetielsellulose, kolloïdale silikondioksied, hidroksipropielmetielsellulose, titaniumdioksied (E171) poliëtileenglikool

Hoe EMERDYNE lyk en die inhoud van die pak
EMERDYNE 10 mg (filmbedekte tablette)
'n Wit tot af-wit, sirkelvormige, bikonvekse, filmbedekte tablet met "ML 60" aan die een kant gedruk, en 'n breeklyn aan die ander kant en met kepe aan weerskante van die breeklyn.

EMERDYNE 20 mg (filmbedekte tablette)
'n Wit tot af-wit, sirkelvormige, bikonvekse, filmbedekte tablet met "ML 61" aan die een kant gedruk, en 'n breeklyn aan die ander kant en met kepe aan weerskante van die breeklyn.

Stulpverpakking (30's)
Tablette word verpak in koue vorm laminaat, 25 µm OPA/45 µm aluminiumfoelie/60 µm PVC as die vormende materiaal en gewone 25 mikron, aluminiumfoelie, 6-8 gsm HSL, as die dekmateriaal.
Aluminium stulpverpakkings van 3 x 10 (30) tablette. Die stulpstroke word in 'n buitenste karton geplaas.

Houer van die Sertifikaat van Registrasie en Vervaardige
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoor Park (Oos),
1 Cussonia Weg, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Hierdie inligtingstuk is laas hersien in
11 April 2021

Registrasienommer(s)
EMERDYNE 10 mg: 45/1.2/0881
EMERDYNE 20 mg: 45/1.2/0882

Toegang tot die ooreenstemmende Professionele Inligting
Die toepaslike professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of stuur e-pos na macleodsrsa@macleodspharma.com of kontak 011 682 1169.

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Professional information removed & dimension change.

1. Product: EMERDYNE 10 & 20 mg (Escitalopram Tablets 10 & 20 mg)	
2. Country: South Africa - Private Market	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 335 (L) x 300 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03914302**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 34837 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03914301**
15. Revision no: 01	**16. File Name :X:\ESCITALOPRAM\SA Private Market\01\EMERDYNE PI & PIL PM03914302.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	11/03/2025				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM03914301	16/08/22	7/11/22
2) Note : Professional information removed & dimension change	PM03914302		