

**Applicant/PHCR:** Trinity Pharma (Pty) Ltd  
**Product Proprietary name:** FELITOR

Film-Coated tablet, 10 mg  
(Escitalopram)

## **PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S5**

**FELITOR** (10 mg Film-coated tablet)

Escitalopram

Sugar free

### **Read all of this leaflet carefully before you start taking FELITOR**

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

#### **1. What FELITOR is and what it is used for**

FELITOR (escitalopram) is a selective serotonin reuptake inhibitor (SSRIs) that belongs to a group of medicines known as antidepressants. These medicines help to normalise serotonin

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levels in the brain. Disruptions to the serotonin system in the brain are believed to be an

important factor in the development of depression and related illnesses.

FELITOR is used to treat depression (major depressive episodes).

## **2. What you need to know before you take FELITOR**

### **Do not take FELITOR**

- if you are hypersensitive (allergic) to escitalopram or any of the other ingredients of FELITOR (listed in section 6).
- if you are a child or adolescent under the age of 18 years
- if you are pregnant or breastfeeding your baby (FELITOR can lead to severe vaginal bleeding after childbirth)
- if you are already taking medicines which belongs to a group called MAO inhibitors (a type of antidepressant medicine). Ask your doctor or pharmacist if you are uncertain
- if you are taking medicines such as pimozide (taken to reduce uncontrolled movements or outbursts of words/sounds caused by Tourette syndrome) that are known to prolong the QT interval (medicines that lengthen the time it takes for the heart muscle to recharge between beats)
- if you have the following condition:  
QT interval prolongation or congenital long QT syndrome (when the heart muscle takes longer to recharge between beats).
- if you are taking linezolid (antibiotic belonging to the oxazolidinone class taken to treat certain bacterial infections)

### **Warnings and precautions**

#### **Take special care with FELITOR:**

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- if you have epilepsy. Treatment with FELITOR should be stopped if seizures occur or if there is an increase in the seizure frequency
- if you suffer from impaired liver function or diabetes (your doctor may need to adjust the dose of medicine you take for these diseases or the dose of FELITOR)
- symptoms like fever, unintentional jerky muscle movements and agitation may develop during treatment. Tell your doctor immediately if you experience these symptoms
- symptoms such as restlessness or difficulty in sitting or standing still can occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms
- if you are taking medicine that lowers you blood sodium, magnesium or potassium (salt) levels
- if you have a tendency to easily develop bleedings or bruises or if you are taking medicine that affect your body's ability to prevent bleeding
- if you are receiving electroconvulsive treatment
- if you have coronary heart disease or have had a heart attack
- if you are taking any herbal medicine containing St. John's wort (a herb used to treat depression)
- if you suffer from glaucoma (a condition of increased pressure within the eyeball, causing gradual loss of sight).
- if you suffer from mood disturbances characterised by rapidly changing moods ranging from mood elevations to depressed states.
- if you experience any sexual dysfunctions, as it may be due to FELITOR.

### **Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants since these medicines all take time to work, usually about two weeks but sometimes longer. If you

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have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

### **Children and adolescents**

If you are under 18 years of age. FELITOR should normally not be used for children and adolescents under 18 years (see 3. What you need to know before you take FELITOR - Do not take FELITOR). Patients under 18 years of age have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger), especially when starting treatment with antidepressants.

### **Other medicines and FELITOR:**

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, so called anticoagulants). Your doctor will probably check the coagulation time of your blood when starting and discontinuing FELITOR in order to verify that your dose of anticoagulant is still adequate
- moclobemide (used to treat depression)
- pimozide (taken to reduce uncontrolled movements or outbursts of words/sounds caused by Tourette syndrome)
- ritonavir (an antiviral medicine taken to treat HIV)

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- tramadol (a pain killer), tryptophan (used in cases of sleeplessness/ depression) and similar medicines in the same group as sumatriptan. If you develop a high temperature, agitation, confusion, tremor and sudden muscle contractions (serotonin syndrome) when you are taking these medicines combined with FELITOR, you should contact your doctor or pharmacist
- Monoamine oxidase inhibitors (MAOIs), containing selegiline (used to treat Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (antibiotic) as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking FELITOR. After stopping FELITOR you must allow 7 days before taking any of these medicines.
- lithium (used in the treatment of manic-depressive disorder)
- imipramine and desipramine (both used to treat depression)
- cimetidine, lansoprazole, and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke)
- St. John's wort (*Hypericum perforatum*) - a herbal remedy used for depression
- acetylsalicylic acid (aspirin) and non-steroidal anti-inflammatory drugs (medicines used for pain relief) or warfarin (medicine to thin the blood, so called anticoagulants)
- mefloquin (used to treat Malaria), bupropion (used to treat depression)
- neuroleptics (medicines to treat schizophrenia, psychosis) due to a possible risk of a lowered threshold for seizures, and antidepressants
- flecainide, propafenone, and metoprolol (used in cardiovascular diseases)
- clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of FELITOR may need to be adjusted.
- Medicines used for the treatment of lowering potassium and magnesium levels.

**FELITOR with food, drink and/or alcohol:**

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FELITOR can be taken with or without food.

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Combining FELITOR with alcohol is not recommended

### **Pregnancy and Breastfeeding**

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 FELITOR.

It is not recommended that you take FELITOR whilst being pregnant or when you are breastfeeding your baby.

### **Driving and using machines**

FELITOR can impair the ability to react, which should be considered in situations when increased attention is needed, such as when driving a car or doing precision work. You are advised not to drive a car or operate machinery until you know how FELITOR affects you.

### **FELITOR contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take FELITOR**

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

Always take FELITOR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is a single tablet taken once daily.

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Your doctor will tell you how long your treatment with FELITOR will last. Do not stop treatment

early. It may take a couple of weeks before you start to feel better. Continue to take FELITOR

even if it takes some time before you feel any improvement in your condition.

If you have the impression that the effect of FELITOR is too strong or too weak, talk to your

doctor or pharmacist.

### *Adults*

#### *Depression*

The normal recommended dose of FELITOR is 10 mg taken as one daily dose. The dose may

be increased by your doctor to a maximum of 20 mg per day.

#### *Children and adolescents (below 18 years of age)*

FELITOR should not be given to children and younger people under the age of 18 (see 3. What you need to know before you take FELITOR - Do not take FELITOR).

### **If you take more FELITOR than you should**

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

### **If you forget to take FELITOR**

If you forget a dose, but remember a little later on that you should have taken it, take that day's dose as usual. However, if a long delay has occurred and the next dose is near, skip the forgotten dose and take the next normal dose at the scheduled time. Do not take a double dose.

### **If you stop taking FELITOR**

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Do not stop your treatment because you are feeling better without consulting with your doctor.

When you do so after consulting your doctor you should go off your treatment gradually as you may suffer severe symptoms of withdrawal.

The risk is higher, when FELITOR has been used for a long time or in high doses or when the dose is reduced too quickly.

Most people find that the symptoms are mild and go away on their own within two weeks.

However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking FELITOR, please contact your doctor.

Discontinuation symptoms may include, but are not restricted to:

- feeling dizzy (unsteady or off-balance)
- feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head
- sleep disturbances (vivid dreams, nightmares, inability to sleep)
- feeling anxious, headaches
- feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling tired, sleepy and yawning more often than usual
- diarrhoea (loose stools), constipation
- fever
- sinusitis
- lower sex drive
- loss of appetite

#### **4. POSSIBLE SIDE EFFECTS**

FELITOR can have side effects.

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If the side effects are troublesome or last for more than 1-2 weeks, you should contact your doctor again.

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

If any of the following happen, stop taking FELITOR 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 an allergic reaction to FELITOR. You may need urgent medical attention or hospitalisation. All of these serious side effects are less frequent.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Less frequent*

- yellowing of the skin and eyes, also called jaundice
- Feeling hostile, suicidal, want to harm yourself
- Panic attack
- Loss of consciousness
- changes in the way your heart beats, for example, if you notice it beating faster/slower
- bleeding in the intestines

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- Blood disorders
- less urine than is normal for you.
- excessive weight loss due to not wanting to eat
- abnormal liver function tests

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent*

- Changes in appetite for food
- Weight gain
- Feeling anxious, restless, have abnormal dreams, loss in sex drive, sexual dysfunction
- Headaches, dizziness, fever
- Experiencing 'pins and needles'; quivering
- Sleep disturbances (insomnia)
- Sinusitis (inflammation of sinuses in the nose)
- Yawning more than is normal for you; tiredness
- Nausea (feeling sick); loose stools (diarrhoea), constipation, vomiting
- Dry mouth
- Increased sweating
- Joint and muscle pain

*Less frequent*

- Weight loss
- Grinding of teeth
- Agitation, nervousness, confusion, aggressiveness.

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- Hallucinations
- Changes in the way things taste
- Changes in vision
- Ringing in the ears
- Nose bleeds
- Abnormal bleeding from the womb; abnormally heavy bleeding at menstruation
- Hair loss
- Swelling due to retained fluid

*Frequency unknown*

- Movement disorders
- Discolouration of the skin; swelling under the skin
- Excessive or inappropriate production of milk
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Do not take FELITOR' in section 2 for more information.

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

**Reporting side effects**

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

**5. How to store FELITOR**

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Store all medicines out of the reach and sight of children.

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Store at or below 30 °C.

Keep the container in the outer carton.

Do not use after the expiry date stated on the carton.

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 FELITOR contains:**

- The active substance is escitalopram oxalate equivalent to 10 mg escitalopram
- The other ingredients are:

#### **Tablet Core**

Colloidal silicon dioxide (anhydrous), Croscarmellose sodium (Ac-Di-Sol), Isopropyl alcohol, Magnesium stearate, Microcrystalline cellulose, Povidone K-30, Talc

#### **Tablet coating**

Hypromellose, Polyethylene glycol 400, Titanium dioxide

### **What FELITOR looks like and contents of the pack**

White to off white, round, biconvex, film coated tablets debossed with break line on both sides, separating '11' and '36' on one side and '10' on other side.

Cold Forming Blister foil (OPA/ALU/PVC) sealed with aluminium foil with heat seal lacquer coating. Printed carton containing 10 tablets, 30 tablets or 100 tablets. Each blister contains 10 tablets.

Not all pack sizes may be marketed.

### **Holder of Certificate of Registration**

TRINITY PHARMA (PTY) LTD.

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18 NORMA JEAN SQUARE, 244 JEAN AVENUE, CENTURION,  
SOUTH AFRICA

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45/1.2/1032

**Access to the corresponding Professional Information**

[www.trinitypharma.co.za](http://www.trinitypharma.co.za)