PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

ADCO TALOMIL 10 mg, 10 mg, film-coated tablets
ADCO TALOMIL 20 mg, 20 mg, film-coated tablets
ADCO TALOMIL 40 mg, 40 mg, film-coated tablets
Citalopram

ADCO TALOMIL 10 mg: Contains sugar (mannitol): 66,275 mg
ADCO TALOMIL 20 mg: Contains sugar (mannitol): 132,55 mg
ADCO TALOMIL 40 mg: Contains sugar (mannitol): 265,10 mg

Read all of this leaflet carefully before you start taking ADCO TALOMIL

- 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.
- **ADCO TALOMIL** 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 the leaflet

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

1. What ADCO TALOMIL is and what it is used for

The active ingredient is citalopram, and belongs to a group of medicines called antidepressants.

ADCO TALOMIL is used for:

- Depression and prevention of relapse.
- Panic disorder, with or without agoraphobia (fear of public places).
- Obsessive-compulsive disorder (OCD) (a disorder pertaining to a recurrent and persistent thought, image or impulse that is unwanted and distressing).

2. What you need to know before you take ADCO TALOMIL

Do not take ADCO TALOMIL:

- If you are hypersensitive (allergic) to citalopram or any of the other ingredients of **ADCO TALOMIL** (listed in section 6).
- If you have severely impaired kidney function (creatinine clearance < 30 mL/min).

- If you or your child is under 18 years of age, as safety and efficacy in children have not been established.
- If you are pregnant or breastfeeding, as safety has not yet been established (see Pregnancy, breastfeeding and fertility).
- If you are using a monoamine oxidase inhibitor (MAOI) (used to treat depression) at the same time. You should wait at least 14 days before stopping the MAOI and starting therapy with **ADCO TALOMIL**. MAOIs should not be taken for 7 days after stopping of **ADCO TALOMIL** treatment.
- If you have a known heart rhythm disorder (called QT
- interval prolongation or congenital long QT syndrome).

Warnings and precautions
Take special care with ADCO TALOMIL:

- If you are an elderly patient, as a lower dose is recommended in the elderly.
- If you have liver problems, as higher blood levels of citalopram may occur, increasing the chance of having unwanted effects. You may need to take a lower dose than a person without liver disease.
- If you have severe kidney disease, as caution is recommended. You may need to take a lower dose than a person without kidney disease.
- If you have seizures or a history thereof. There is an increased risk of seizures with antidepressant medicines, such as **ADCO TALOMIL**. **ADCO TALOMIL** should be used with caution in patients with controlled epilepsy and avoided in patients who are poorly-controlled epileptics. Care is advised if you are receiving electroconvulsive therapy.
- If you have mania or history of mania, as a change towards the manic phase may occur. **ADCO TALOMIL** should be stopped if you are suffering from mania.
- If you have a panic disorder.
- If you have low blood levels of sodium.
- If you experience symptoms such as restlessness or difficulty in sitting or standing still. These symptoms are most likely to occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.
- If you suffer from a psychosis.
- If you have any heart problems, as **ADCO TALOMIL** may reduce your heart rate. Caution is advised in patients with pre-existing slow heart rates.
- If you suffer from diabetes mellitus (sugar diabetes) as **ADCO TALOMIL** may cause a change in your blood sugar control.
- If you experience any of the following symptoms: high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome. You doctor will discontinue your treatment of **ADCO TALOMIL** and treat you symptomatically.
- If you have or had a history of a bleeding disorder or if you are pregnant (see Pregnancy, breastfeeding and fertility in section 2).
- If you or your child has a major depressive disorder and have thoughts about killing or harming yourself, currently or at any time in the past, contact your doctor or go to a

hospital immediately. If the decision is made to discontinue treatment, **ADCO TALOMIL** dose should be tapered.
- If you have an abnormally slow or fast heart rate, recently had a heart attack or suffer from heart failure. Your doctor will monitor the condition of your heart and may perform an electrocardiogram (ECG).

Children and adolescents
Safety and efficacy in children under 18 years of age have not been established.

Other medicines and ADCO TALOMIL
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines may cause an interaction when used in combination with **ADCO TALOMIL** and should not be used together:
- MAOIs (such as phenelzine, moclobemide or selegiline), imipramine, selective serotonin reuptake inhibitors (such as sertraline, fluoxetine or venlafaxine) (used to treat depression, major depressive disorder or anxiety disorders).
- Sumatriptan (used to treat migraine and cluster headaches).
- Tramadol (used to treat severe pain).
- Oxitriptan or tryptophan (used to treat depression and sleeping problems).
- St John's wort (a herbal remedy, used to treat depression).
- Sparteine (used to treat heart disorders).
- Alcohol should not be used with **ADCO TALOMIL**.
- Warfarin (used to prevent blood from clotting).
- Cimetidine (used to treat heartburn).
- Antidysrhythmics (used to treat heart rhythm disorders).
- Phenothiazine derivatives, pimozide or haloperidol (used to treat schizophrenia and psychotic disorders).
- Sparfloxacin, moxifloxacin, erythromycin or linezolid (used treat bacterial infections).
- Pentamidine (used to treat fungal infections).
- Halofantrine (used to treat malaria).
- Mizolastine (used to treat allergic conditions).

ADCO TALOMIL with food and drink
ADCO TALOMIL can be taken with or without food.

Pregnancy, breastfeeding and fertility
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 this medicine.
Safety in pregnancy and breastfeeding has not yet been established. **ADCO TALOMIL** is excreted into breast milk.

If you take **ADCO TALOMIL** near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor, nurse or other health care professional should be aware that you are taking **ADCO TALOMIL** so they can advise you.

Driving and using machines
ADCO TALOMIL may impair your ability to drive and operate machinery. Do not drive or operate machinery until you know how **ADCO TALOMIL** affects you.
It is not always possible to predict to what extent **ADCO TALOMIL** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **ADCO TALOMIL** affects them.

3. How to take ADCO TALOMIL

Do not share medicines prescribed for you with any other person.
Always take **ADCO TALOMIL** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

It can be taken in the morning or evening and not necessarily with food. **ADCO TALOMIL** should be taken as a single daily dose.

Adults
Treating depression
The usual dose is 20 mg **ADCO TALOMIL** taken once daily. This dose may be increased to a maximum of 40 mg daily by your doctor.
You will normally be asked to keep taking **ADCO TALOMIL** for at least 6 months.

Treating panic disorder
The usual dose is 10 mg for the first week, before increasing the dose to 20 mg daily.
This dose may be further increased to a maximum of 40 mg daily by your doctor.

Treating obsessive-compulsive disorder (OCD)
The usual starting dose is 20 mg daily as a single dose. This dose can be increased by your doctor to a maximum of 40 mg daily.
The exact dose will depend on how your condition responds to treatment.

People with kidney problems: Your doctor will determine the dose that is suitable for you.
People with liver problems: The usual staring dose for the first two weeks is 10 mg daily. Depending on your response, the dose may be increased to a maximum of 20 mg daily by your doctor.

Children and adolescents (under the age of 18 years)
The use of **ADCO TALOMIL** is not recommended, as safety and efficacy have not been established in this age group.

Elderly (patients above 65 years of age)
For elderly patients, the dose should be decreased to half of the recommended dose: 10 to 20 mg daily as a single dose. The recommended maximum daily dose for elderly patients is 20 mg.

Your doctor will tell you how long your treatment with **ADCO TALOMIL** will last.
If you have the impression that the effect of **ADCO TALOMIL** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ADCO TALOMIL than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
If overdosage should occur, it may give rise to tiredness, weakness, sedation, dizziness, tremor, nausea and sleepiness.

If you forget to take ADCO TALOMIL
Do not take a double dose to make up for forgotten individual doses.
If you forget to take a dose of **ADCO TALOMIL**, take it as soon as you remember.

If you stop taking ADCO TALOMIL
Stopping **ADCO TALOMIL** quickly may cause symptoms such as dizziness, nausea and numbness or tingling in hands or feet, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). These are usually non-serious and disappear within a few days. When you have completed your course of treatment, the dose of **ADCO TALOMIL** is usually reduced gradually over a couple of weeks.

4. Possible side effects
ADCO TALOMIL can have side effects.
Not all side effects reported for **ADCO TALOMIL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ADCO TALOMIL**, please consult your health care provider for advice.

If any of the following happens, stop taking **ADCO TALOMIL** 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 a serious allergic reaction to **ADCO TALOMIL**. You may need urgent medical attention or hospitalisation.

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

- You start having fits for the first time or fits that you have suffered from in the past become more frequent.
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium (hyponatraemia) (particularly if you are an elderly person).
- Fast, irregular heartbeats (tachycardia) or slow, irregular heartbeats (bradycardia).
- *Frequency unknown:*
- You experience high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome.
- If you have thoughts of harming or killing yourself at any time.
- Hepatitis (yellowing of the skin and eyes, also called jaundice.
- Long QT syndrome (a disorder of the electrical activity of the heart), which can cause sudden, uncontrollable, dangerous dysrhythmias (problems with the rate or rhythm of the heartbeat) in response to exercise or stress.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage) has been reported. See Pregnancy, breastfeeding and fertility in section 2 for more information.

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

Tell your doctor as soon as possible if you notice any of the following:
Frequently:

- Sleeping problems, feeling restless, feeling nervous, sleepiness.
- Problems with ejaculation and erection (in men).
- Failing to reach an orgasm (in women).
- Nausea (feeling sick), dry mouth.
- Unusual weakness or tiredness.

Less frequently:

- Flow of breast milk in men or in women who are not breastfeeding (galactorrhoea).
- Loss of body mass (anorexia), weight changes.
- Anxiety, panic attacks, mania (feeling elated or over excited.
- Feeling agitated or confused, problems concentrating.
- Involuntary movements (parkinsonian disorders), tremor.
- Large pupils (the dark center of the eye), visual disturbances.
- Bleeding disorders including skin and mucosal bleeding (ecchymosis).
- Red- or purple-coloured spots on the skin.
- A sudden increase in blood pressure when you stand up.
- Blocked nose, yawning.
- Increase in saliva (drooling), vomiting (being sick), diarrhoea (loose stools), indigestion.
- Sweating.
- Joint pain, muscle pain, loss of sensation.

- Bladder or urination problems.

Frequency unknown:
- Irregular menstrual periods.
- Feeling aggressive, impulsive behaviour.
- Involuntary movements of the muscles or inability to sit still (akathisia).
- Tingling or numbness in the hands or feet.
- Headache, dizziness, irritability, neuroleptic malignant syndrome (a serious reaction, characterised by fever, and muscular stiffness and sweating).
- Constipation.
- Liver problems, abnormal liver function tests.
- Sensitivity to sunlight.
- Hives, hair loss (temporary).

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 **ADCO TALOMIL**.

5. How to store ADCO TALOMIL
Store all medicines out of reach of children.
Store at or below 25 °C in a dry place.
Keep blisters in outer carton until required for use.
Do not use after the expiry date on the label.
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 ADCO TALOMIL contains
The active substance is citalopram.
The other ingredients are:
Tablet core: Colloidal silica anhydrous, magnesium stearate, mannitol, microcrystalline cellulose.
Coating: Hypromellose, macrogol 6000, titanium dioxide.

What ADCO TALOMIL looks like and contents of the pack
ADCO TALOMIL 10 mg: Round, biconvex, unscored, 6 mm, coated, white tablets.
ADCO TALOMIL 20 mg: Round, biconvex, scored on both sides with side scores, 8 mm, coated, white tablets.

ADCO TALOMIL 40 mg: Round, biconvex, scored on both sides with side scores, 10 mm, coated, white tablets.

Blister packs of colourless, transparent plastic blisters and aluminium foil, containing 28 or 30 tablets.

Holder of Certificate of Registration
Adcock Ingram Limited
1 New Road,
Erand Gardens
Midrand, 1685
Private Bag X69
Bryanston 2021

The leaflet was last revised in
19 April 2021

Registration number
ADCO TALOMIL 10 mg: 35/1.2/0271
ADCO TALOMIL 20 mg: 35/1.2/0272
ADCO TALOMIL 40 mg: 35/1.2/0273

Namibia: ADCO TALOMIL 20 mg: NS3 04/1.2/1121

adcock ingram