

**Applicant/PHCR:** AUROGEN SA (PTY) LTD

**Product proprietary name:** TABUCYM

**Submitted:** 28/09/2020

**Dosage form and strength:** CAPSULES 30 mg and 60 mg

**Submitted:** 15/12/2020

### 1.3.2 Patient Information Leaflet approved

**S5**

#### PATIENT INFORMATION LEAFLET

**TABUCYM 30** (capsule)

**TABUCYM 60** (capsule)

Duloxetine hydrochloride.

Contains sugar: 78 mg and 156 mg of sucrose respectively.

**Read all of this leaflet carefully before you start taking TABUCYM.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TABUCYM 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 TABUCYM is and what it is used for
2. What you need to know before you use TABUCYM
3. How to use TABUCYM
4. Possible side effects
5. How to store TABUCYM
6. Contents of the pack and other information

**1. What TABUCYM is and what it is used for**

TABUCYM contains the active substance duloxetine. Duloxetine increases the levels of serotonin and noradrenaline in the nervous system.

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TABUCYM is used to treat:

- depression
- diabetic neuropathic pain (often described as burning, stabbing, stinging, shooting or aching or like an electric shock. There may be loss of feeling in the affected area, or sensations such as touch, heat, cold or pressure may cause pain).

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

### **Do not take TABUCYM:**

- Are allergic to duloxetine or any of the other ingredients of this medicine
- Are pregnant or breastfeeding
- have liver disease
- have severe kidney disease
- are taking or have recently taken within the last 14 days, another medicine known as a monoamine oxidase inhibitor (MAOI)
- TABUCYM should not be used in children under 18 years of age as safety has not been established.

### **Warnings and precautions**

#### **Take special care with TABUCYM:**

- are taking other medicines to treat depression
- are taking St. John's Wort, a herbal treatment (*Hypericum perforatum*)
- have kidney disease
- have had seizures (fits)
- suffer from bipolar disorder
- have eye problems, such as certain kinds of glaucoma (increased pressure in the eye)
- have a history of bleeding disorders (tendency to develop bruises)

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- are at risk of low sodium levels (for example if you are taking diuretics, especially if you are elderly)
- if you have high blood pressure
- are currently being treated with another medicine which may cause liver damage or if you use alcohol in substantial amounts
- TABUCYM may cause a sensation of restlessness or an inability to sit or stand still.
- If you are depressed 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.

#### **Other medicines and TABUCYM:**

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

TABUCYM may have an effect on other medicines or other medicines may have an effect on TABUCYM.

- Monoamine Oxidase Inhibitors (MAOIs): You should not take TABUCYM if you are taking, or have recently taken (within the last 14 days) another antidepressant medicine called a monoamine oxidase inhibitor (MAOI). Examples of MAOIs include moclobemide (an antidepressant) and linezolid (an antibiotic). Taking a MAOI together with many prescription medicines, including TABUCYM, can cause serious or even life-threatening side effects. You must wait at least 14 days after you have stopped taking an MAOI before you can take TABUCYM. Also, you need to wait at least 5 days after you stop taking TABUCYM before you take a MAOI.

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- Medicines that cause sleepiness: These include medicines prescribed by your doctor including benzodiazepines, strong painkillers, antipsychotics, phenobarbitone, antihistamines.
- Medicines that increase the level of serotonin:  
Triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), SNRIs (such as venlafaxine), tricyclic antidepressants (such as clomipramine, amitriptyline), pethidine, St John's Wort. These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with TABUCYM, you should see your doctor.
- Oral anticoagulants or antiplatelet medicines:  
Medicines which thin the blood or prevent the blood from clotting. These medicines might increase the risk of bleeding.

The main ingredient of TABUCYM, duloxetine, is also used in other medicines for other conditions. You should not take one of these medicines at the same time as TABUCYM. Check with your doctor if you are already taking other medicines containing duloxetine.

#### **TABUCYM with food and drink**

TABUCYM may be taken with or without food.

#### **Pregnancy, breastfeeding and fertility**

You should not take TABUCYM if you are pregnant (see 'Do not take TABUCYM').

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking TABUCYM.

Tell your doctor if you are breastfeeding. The use of

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TABUCYM while breastfeeding is contraindicated (see Do r  
TABUCYM).

### **Driving and using machines**

TABUCYM may make you feel sleepy or dizzy. Do not drive or use any tools or machines until you know how TABUCYM affects you.

### **TABUCYM contains sucrose:**

TABUCYM contains sucrose, which is a type of sugar.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **3. How to take TABUCYM**

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

TABUCYM is for oral use. You should swallow your capsule whole with a drink of water.

For depression and diabetic neuropathic pain:

The usual dose of TABUCYM is one capsule (60 mg duloxetine) once a day, but your doctor will prescribe the dose that is right for you.

Always take TABUCYM exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with TABUCYM will last. Do not stop taking your treatment without consulting your doctor. If you have the impression that the effect of TABUCYM is too strong or too weak, talk to your doctor or pharmacist.

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**If you take more TABUCYM than you should**

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

If you take more than required dose you may experience symptoms that include sleepiness, coma, serotonin syndrome (a rare reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles) fits, vomiting and fast heart rate.

**If you forget to take TABUCYM**

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses

**4. Possible side effects**

TABUCYM can have side effects.

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

If any of the following happens, stop taking TABUCYM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty in breathing or dizziness with swollen tongue or lips

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TABUCYM. 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:

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- suicidal thoughts,
- suicidal behaviour, self-harm, mania (over activity, racing thoughts and decreased need for sleep), hallucinations, aggression and anger,

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

Tell your doctor if you notice any of the following:

**The following side effects occur frequently:**

- headache, feeling sleepy
- feeling sick (nausea), dry mouth
- lack of appetite
- anxiety, reduced sex drive, difficulty or failure to experience orgasm, unusual dreams
- dizziness, feeling sluggish, tremor, numbness,  
including numbness, pricking or tingling of the skin
- blurred eyesight
- tinnitus (hearing sound in the ear when there is no external sound)
- feeling the heart pumping in the chest,
- increased blood pressure, flushing
- increased yawning
- constipation, diarrhoea, stomach pain, being sick (vomiting), heartburn or indigestion,  
breaking wind
- increased sweating, (itchy) rash
- muscle pain, muscle spasm
- painful urination, frequent urination
- problems getting an erection ,changes in ejaculation
- falls (mostly in elderly people), fatigue

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- weight loss

**The following side effects occur less frequently:**

- throat inflammation that causes a hoarse voice
- grinding or clenching the teeth, feeling disorientated, lack of motivation
- sudden involuntary jerks or twitches of the muscles, sensation of restlessness or an inability to sit or stand still, feeling nervous,
- difficulty concentrating, changes in sense of taste,
- difficulty controlling movement e.g. lack of coordination or involuntary movements of the muscles, restless legs syndrome
- large pupils (the dark centre of the eye), problems with eyesight
- feeling of dizziness or “spinning” (vertigo), ear pain
- fast and/or irregular heart beat
- fainting, dizziness, lightheadedness or fainting on standing up, cold fingers and/or toes
- throat tightness, nose bleeds
- vomiting blood, or black tarry stools (faeces),
- gastroenteritis, burping, difficulty swallowing
- inflammation of the liver that may cause abdominal pain and yellowing of the skin or whites of the eyes
- night sweats, hives, cold sweats, sensitivity to sunlight, increased tendency to bruise
- muscle tightness, muscle twitching
- difficulty or inability to pass urine, difficulty to start urinating, needing to pass urine during the night, needing to pass more urine than normal, having a decreased urine flow

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- abnormal vaginal bleeding, abnormal periods, including heavy, painful, irregular or prolonged periods, unusually light or missed periods, pain in the testicles or scrotum
- chest pain, feeling cold, thirst, shivering, feeling hot
- abnormal gait
- weight gain

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

### Reporting of side effects

If you get any 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 Reaction Reporting Form”, found online under SAHPRA’s publications: <https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZA>. By reporting side effects, you can help provide more information on the safety of TABUCYM.

### 5. How to store TABUCYM

Store at or below 25 °C.

Keep the blisters in the carton until required for use.

#### **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**

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 TABUCYM contains**

The other ingredients of TABUCYM are hypromellose, hydroxy propyl cellulose, crospovidone, talc, triethylcitrate and titanium dioxide.

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**TABUCYM:** The capsule shell contains gelatin, sodium laury sulphate, FD & C Blue 2 (C.I. No: 73015), titanium dioxide (C.I. No: 77891).

**TABUCYM:** The black ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide (C.I. No: 77499) and potassium hydroxide.

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

##### **TABUCYM 30:**

Blue opaque / white opaque, size '3' hard gelatin capsule filled with white to off white pellets and imprinted with 'DLX' on blue opaque cap and '30' on white opaque body with black ink.

##### **TABUCYM 60:**

Blue opaque / green opaque, size '1' hard gelatin capsule filled with white to off white pellets and imprinted with 'DLX' on blue opaque cap and '60' on green opaque body with black ink..

##### **Blister pack:**

Capsules are packed in 60 micron PVC film /25 micron polyamide/ 60 micron aluminium foil/ 60 micron PVC film as the forming material and 25 µm aluminum foil with 7 gsm heat seal lacquer as the lidding material.

**Pack size: 30's** – Each carton contains 3 blisters of 10 capsules each.

##### **HDPE Pack:**

White opaque round 40 ml HDPE container with 33 mm neck finish closed with 33 mm white opaque polypropylene stock ribbed closure with wad having induction sealing liner containing 1 no of 1 g silica gel sachet.

**Pack size: 30's** – One HDPE container contains 30 Capsules

#### **HOLDER OF THE CERTIFICATE OF REGISTRATION**

Aurogen SA (Pty) Ltd

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South Africa

**Registration number**

**TABUCYM 30: 47/1.2/0095**

**TABUCYM 60: 47/1.2/0096**