PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS: **S4**

CADIATEV, 2 mg, prolonged-release tablet

Melatonin

Contains sugar (lactose monohydrate 80 mg per tablet).

Read all of this leaflet carefully before you start taking CADIATEV:

- 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.
- CADIATEV 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 CADIATEV IS AND WHAT IT IS USED FOR

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CADIATEV

3. HOW TO TAKE CADIATEV

4. POSSIBLE SIDE EFFECTS

5. HOW TO STORE CADIATEV

6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT CADIATEV IS AND WHAT IT IS USED FOR:

The active substance of CADIATEV, melatonin, belongs to a natural group of hormones produced by the body.

CADIATEV is used on its own for the short-term (up to 13 weeks) treatment of primary insomnia (persistent difficulty in getting to sleep or staying asleep, or poor quality of sleep) in patients aged 55 years and older. 'Primary' means that the insomnia does not have any identified cause, including any medical, mental, or environmental cause.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CADIATEV:

Do not take CADIATEV:

- if you are hypersensitive (allergic) to melatonin or to any other ingredients of CADIATEV (listed in **section 6**)
- if you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions:

Special care should be taken with CADIATEV:

- if you suffer from liver or kidney problems. No studies on the use of CADIATEV in people with liver or kidney diseases have been performed, you should speak to your doctor before taking CADIATEV as its use is not recommended.
- if you have been told you suffer from an autoimmune disease (where the body is 'attacked' by its own immune system). No studies on the use of CADIATEV in people with auto-immune diseases have been performed; therefore, you should speak to your doctor before taking CADIATEV as its use is not recommended.
- smoking may make CADIATEV less effective, because the components of tobacco smoke can increase the breakdown of melatonin by the liver.

Children and adolescents:

Do not give this medicine to children below 18 years as it has not been tested and its effects are unknown.

Other medicines and CADIATEV:

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

(This includes all complementary or traditional medicines.)

Fluvoxamine (used for the treatment of depression and obsessive-compulsive disorder), psoralens (used in the treatment of skin disorders e.g., psoriasis), cimetidine (used in the treatment of stomach problems such as ulcers), quinolones and rifampicin (used in the treatment of bacterial infections), oestrogens (used in contraceptives or hormone replacement therapy) and carbamazepine (used in the treatment of epilepsy).
Adrenergic agonists/antagonists (such as certain types of medicines used to control blood pressure by constricting blood vessels, nasal decongestants, blood pressure lowering medicines), opiate agonists/antagonists (such as medicines used in the treatment of drug addiction), prostaglandin inhibitors (such as nonsteroidal anti-inflammatory medicines), antidepressant medication, tryptophan, and alcohol.
Benzodiazepines and non-benzodiazepine hypnotics (medicines used to induce sleep such as zaleplon, zolpidem and zopiclone).
Thioridazine (for the treatment of schizophrenia) and imipramine (for the treatment of depression).

CADIATEV with food, drink, and alcohol:

Take CADIATEV after you have eaten. Do not drink alcohol before, during or after taking CADIATEV, because it reduces the effectiveness of CADIATEV.

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 healthcare provider for advice before taking CADIATEV.

Do not take CADIATEV if you are pregnant or breastfeeding your baby while taking CADIATEV.

Driving and using machines:

CADIATEV might cause tiredness, dizziness, fainting, or blurred vision.

It is not always possible to predict to what extent CADIATEV may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or using machines until you are aware of the measure to which CADIATEV affects you.

CADIATEV contains lactose monohydrate:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking CADIATEV prolonged-release tablets.

3. HOW TO TAKE CADIATEV:

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

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

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

The recommended dose is one CADIATEV tablet (2 mg) taken daily by mouth, after food, 1 to 2 hours before bedtime. This dosage may be continued for up to thirteen weeks.

You should swallow the tablet whole. CADIATEV tablets should not be crushed or cut in half.

If you take more CADIATEV than you should:

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

If you forget to take CADIATEV:

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS:

CADIATEV can have side effects.

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

If any of the following happens, stop taking CADIATEV and tell your doctor immediately and 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 reaction to CADIATEV. 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:

- chest pain

- heart irregularities.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- a reactivation of the chickenpox virus in the body, causing a painful rash
- reduced number of white blood cells in the blood
- reduced blood platelets, which increases risk of bleeding or bruising
- a high level of a certain type of fat (triglycerides) in the blood
- low serum calcium levels in the blood, low sodium levels in the blood
- irritability, nervousness, restlessness, insomnia, abnormal dreams, nightmares, anxiety, migraine, headache
- altered mood, aggression, agitation, crying, stress symptoms, early morning awakening, increased sex drive, depressed mood, depression
- restlessness associated with increased activity, dizziness, tiredness, disturbance in attention, memory impairment
- lethargy (tiredness, lack of energy), restless legs syndrome, poor quality sleep, 'pins and needles' feeling, migraine, fainting
- feeling of drowsiness
- visual impairment, excessive tearing
- blurred vision
- vertigo (a feeling of dizziness or 'spinning'), episodes of dizziness and a sensation of spinning with certain head movements
- high blood pressure, hot flushes
- upper abdominal pain, stomach pain, indigestion, mouth ulceration, dry mouth, nausea
- acid reflux, stomach disorder, inflammation of the stomach lining

- blistering in the mouth, tongue ulceration, stomach upset, vomiting, abnormal bowel sounds, wind, excess saliva production, bad breath, abdominal discomfort, gastric disorder
- abnormal liver function, increased liver enzyme functions, abnormal increase of bilirubin in the blood
- eczema, skin rash, hand dermatitis, itchy rash, nail disorder, psoriasis, night sweats, itching, rash, dry skin, excessive sweating
- presence of red blood cells in the urine
- excretion of glucose in the urine
- excess proteins in the urine, passing large volumes of urine, urinating during the night
- pain in extremities, arthritis, muscle spasms, neck pain, night cramps
- menopausal symptoms
- prolonged erection that might be painful, inflammation of the prostate gland,
- feeling of weakness, tiredness, pain, thirst
- changes in the composition of your blood which could cause yellowing of the skin or eyes, inflammation of the skin
- weight increase
- abnormal blood electrolytes.

Side effects with unknown frequency:

- swelling of mouth or tongue, swelling of the skin
- abnormal milk secretion.

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, 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 CADIATEV.

5. HOW TO STORE CADIATEV:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Blisters packs: Store at or below 25 °C. Store in the original package in order to protect from light.

HDPE containers: Store at or below 30 °C. Store in the original package in order to protect from light.

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 CADIATEV contains:

CADIATEV contains 2,0 mg melatonin per prolonged-release tablet.

The other ingredients are ammonio methacrylate copolymer type B, calcium hydrogen phosphate dihydrate, lactose monohydrate, silica (colloidal anhydrous), talc and magnesium stearate.

What CADIATEV looks like and contents of the pack:

White to off-white, oval, biconvex prolonged-release tablets with no scoring, marked ‘A6’ on one side.

The tablets are packaged in blister packs (PVC/PVdC/Al or PVC/PE/PVdC/PE/PVC/Al) of 20, 21, 30 or 90 prolonged-release tablets in an outer cardboard carton, and plastic (HDPE) containers closed with a sealed plastic cap (PP-closure) with desiccant integrated in the cap containing 100 prolonged release-tablets.

Not all pack sizes will be marketed.

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

2090

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1