

## **SCHEDULING STATUS**

S5

## **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**EPRAJUB 5** film coated tablet

**EPRAJUB 10** film coated tablet

**EPRAJUB 15** film coated tablet

**EPRAJUB 20** film coated tablet

**Please read all of this leaflet carefully before you start taking EPRAJUB film coated tablets.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **EPRAJUB** 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.

### **1. WHAT EPRAJUB CONTAINS**

#### ***Active ingredient:***

#### **EPRAJUB 5:**

Each film coated tablet contains escitalopram oxalate equivalent to 5 mg escitalopram.

#### **EPRAJUB 10:**

Each film coated tablet contains escitalopram oxalate equivalent to 10 mg escitalopram.

#### **EPRAJUB 15:**

Each film coated tablet contains escitalopram oxalate equivalent to 15 mg escitalopram.

#### **EPRAJUB 20:**

Each film coated tablet contains escitalopram oxalate equivalent to 20 mg escitalopram.

#### ***Inactive ingredients:***

Anhydrous colloidal silica, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, Opadry White (containing macrogol, hypromellose and titanium dioxide) and talcum.

## **2. WHAT EPRAJUB IS USED FOR**

**EPRAJUB** is used for:

- Major depressive episodes.
- Panic disorder.

## **3. BEFORE YOU TAKE EPRAJUB**

**Do not take EPRAJUB:**

- If you are allergic (hypersensitive) to escitalopram or any of the ingredients in the formulation (see **WHAT EPRAJUB CONTAINS**).
- If you are born with or have had an episode of abnormal heart rhythm (seen on the electrocardiogram (ECG), which is an examination to evaluate how your heart is functioning).
- If you are taking any other medication for depression such as monoamine oxidase inhibitors (MAOIs). At least 14 days should elapse between stopping such medication and starting with **EPRAJUB**. MAOIs should not be started within 7 days after discontinuation of **EPRAJUB**.
- If you are pregnant or breastfeeding, do not take **EPRAJUB**.
- **EPRAJUB** should not be used by children under the age of 18 years.

**Take special care with EPRAJUB:**

- If you are an elderly person.
- If you have any liver or kidney disorder.
- If you have epilepsy (fits/seizures) or have a history thereof.
- If you receive electroconvulsive therapy.
- If you have mania or a history of mania.
- If you have a heart disorder.
- If you have diabetes (high blood sugar).
- If you have thoughts of harming yourself or committing suicide.
- If you have a tendency to easily develop bleedings or bruises.

- If you have a panic disorder, you may experience increased anxiety symptoms at the start of your **EPRAJUB** treatment. Your doctor will therefore start you on a low dose to reduce your risk of having a panic attack.
- If you have a movement disorder characterised by a feeling of inner restlessness. Your doctor will control your dosage.
- If you have a decreased level of sodium in your blood.
- If you are taking medicines with serotonergic effects (see **Taking other medicines with EPRAJUB**).
- If you are using St John's wort, as it may result in an increased incidence of adverse reactions.
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

#### **Taking EPRAJUB with food and drink:**

The **EPRAJUB** tablets can be taken with or without food.

#### **Pregnancy and breastfeeding:**

**DO NOT** take **EPRAJUB** if you are pregnant or suspect that you are pregnant.

**DO NOT** take **EPRAJUB** if you are breastfeeding.

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

#### **Driving and using machinery:**

**EPRAJUB** may impair your ability to drive and use machinery. Do not drive a vehicle or use machinery if you feel dizzy, tired or drowsy while taking **EPRAJUB**. Please make sure you know how **EPRAJUB** affects you before driving or using machinery.

#### **Taking other medicines with EPRAJUB:**

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

The following may interact with **EPRAJUB**:

- Linezolid, sparfloxacin, moxifloxacin, erythromycin or pentamidine (used to treat bacterial infections).
- Selegiline (used to treat early-stage Parkinson's disease, depression or memory loss).
- Imipramine, desipramine, clomipramine, moclobemide, nortriptyline, amitriptyline, fluoxetine, paroxetine, sertraline or bupropion (used to treat depression).
- Tramadol (used to treat moderate to severe pain).
- Sumatriptan (used to treat migraine).
- Avoid the consumption of alcohol.
- Warfarin (used to prevent blood from clotting).
- Cimetidine or omeprazole (used to treat stomach ulcers or heartburn).
- Antidysrhythmics e.g. quinidine, procainamide, amiodarone, sotalol, metoprolol, flecainide or propafenone (used to treat abnormal heart rhythms).
- Chlorpromazine, fluphenazine, chlorprothixene (used to treat various psychiatric disorders, including schizophrenia).
- Haloperidol (used in the treatment of schizophrenia, acute psychosis, mania, intractable hiccups, agitation and severe anxiety).
- Halofantrine or mefloquin (used to treat malaria).
- Mizolastine (used to treat allergies, hives (urticaria), and other allergic conditions).
- Lithium (used to treat bipolar disorders).
- St John's wort (a herbal remedy, used to treat depression).
- Nonsteroidal anti-inflammatory medicines, e.g. ibuprofen, diclofenac or aspirin (used to treat pain and inflammation).
- Risperidone, thioridazine (used to treat certain mental or mood disorders, such as schizophrenia or bipolar disorder).
- Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life-threatening heart rhythm disorders.

#### **4. HOW TO TAKE EPRAJUB**

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

You and your doctor should talk about the benefits and risks of treatment with **EPRAJUB**.

Always take **EPRAJUB** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The recommended dosage of **EPRAJUB** is one tablet once a day either in the morning or the evening, with or without food.

The dose of **EPRAJUB** will be different for different patients and may depend on a number of things, including what the medicine is being used for, and whether or not other medicines are also being taken.

If you have the impression that the effect of **EPRAJUB** is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more EPRAJUB than you should:**

In the event of overdosage, consult your doctor or pharmacist, if neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and the remaining tablets with you so the doctor will know what you have taken.

#### **If you missed a dose of EPRAJUB:**

Do not take a double dose to make up for forgotten doses. If you forget to take a dose of **EPRAJUB**, take your dose as usual at the next scheduled time.

#### **Effects when treatment with EPRAJUB is stopped:**

If you want to interrupt your **EPRAJUB** treatment, please discuss this with your doctor beforehand. He/she might need to take appropriate measures. Do not stop taking **EPRAJUB** on your own initiative without discussing this with your doctor. When stopping treatment with **EPRAJUB**, your doctor will gradually reduce your dose over a number of weeks or months. This should help reduce the possibility of withdrawal effects.

## 5. POSSIBLE SIDE EFFECTS

**EPRAJUB** may have side effects. Not all side effects reported for **EPRAJUB** are included in this leaflet.

**Should your general health worsen or if you experience any untoward effects while taking EPRAJUB, please consult your doctor, pharmacist or other healthcare professional for advice.**

If any of the following happens, stop taking **EPRAJUB** 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, itching, urticaria (hives).
- Fainting.

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

- Seizures (fits).
- Symptoms of serotonin syndrome, characterised by high fever, agitation, confusion, trembling and abrupt contractions of muscles.
- Fast or slow irregular heartbeat and/or fainting, which could be symptoms of a life-threatening condition known as torsades de pointes.

### *Frequency unknown:*

- Difficulty urinating.
- Yellowing of your skin and the white in your eyes are signs of liver function impairment, also called jaundice.

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:

*Frequent:*

- Anxiety, restlessness, abnormal dreams and women may experience difficulties achieving orgasm.
- Decreased or increased appetite or weight gain.
- Sleeping problems (insomnia), sleepiness (somnolence), dizziness, unusual weakness, headache, burning or prickling sensation (paraesthesia), involuntary shaking of your body or limbs (tremor).
- Blocked or runny nose (sinusitis), yawning.
- Feeling sick (nausea), vomiting (being sick), constipation, diarrhoea, dry mouth, indigestion and/or bloatedness.
- Increased sweating.
- Muscle and/or joint pain.
- Sexual disturbances (delayed ejaculation, problem with erection), decreased sexual drive.
- High fever, swelling of soft tissues as a result of excess fluid accumulation (oedema).

*Less frequent:*

- Clenching and grinding of your teeth (bruxism).
- Agitation, nervousness, panic attack, confusion, aggression, loss of contact with your own personal reality accompanied by feelings of unreality (depersonalisation), seeing or feelings things that do not exist (hallucinations).
- Weight loss.
- Taste disturbance, loss of consciousness, restlessness, poor concentration, unusual tiredness, movement disorders (involuntary movements of the muscles), inability to sit still (akathisia).
- Enlarged pupils (mydriasis), blurred vision, ringing in the ears (tinnitus).
- Nose bleed (epistaxis).
- Blood in your stools.

- Hair loss (temporary).
- Bleeding from the uterus that is not associated with menstruation, abnormally heavy or extended menstrual flow.
- Flow of milk in women that are not nursing.
- Painful erection of the penis.

*Frequency unknown:*

- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia).
- Build-up of fluids as well as abnormally low sodium levels (hyponatraemia).
- Anorexia.
- Elevated mood state (mania).
- Suicide-related behaviour, thoughts of harming yourself or thoughts of killing yourself.
- Angry behaviour (hostility).
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension).
- Increase in saliva.
- Abnormal liver function test (increased amounts of liver enzymes in your blood).
- Lack or loss of strength and energy (asthenia).
- Increased risk of bone fractures.

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

## **6. STORING AND DISPOSING OF EPRAJUB**

- Store at or below 25 °C. Protect from light.
- Keep blister strips in outer 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 and sewerage systems (e.g. toilets).



## **7. PRESENTATION OF EPRAJUB**

**EPRAJUB** is packed into transparent PVC/PE/PVDC film / silver aluminium foil blister strips or OPA-Alu-PVC/Alu / silver aluminium foil blister strips.

7 or 10 film coated tablets are packed per blister strip.

2 x 14 tablet blister strips (28 film coated tablets) or 3 x 10 tablet blister strips (30 film coated tablets) are packed in an outer cardboard carton.

## **8. IDENTIFICATION OF EPRAJUB**

### **EPRAJUB 5:**

White, round, biconvex, film coated tablet, debossed with 'B2' on one side and 'C' on the other side.

### **EPRAJUB 10:**

White, oval shaped, biconvex, film coated tablet, with score-line on one side, debossed with 'B' on left side of score-line and '3' on right side of score-line and with 'C' on the other side.

### **EPRAJUB 15:**

White, modified capsule shaped, biconvex, film coated tablet with score-line on both sides, debossed with '15' on one side of the score-line, on one side of the tablet.

### **EPRAJUB 20:**

White, oval shaped, biconvex, film coated tablet with score-line on one side, debossed with 'B4' on left side of score-line and 'C' on right side of score-line and plain on the other side.

## **9. REGISTRATION NUMBERS**

**EPRAJUB 5:** 46/1.2/0392

**EPRAJUB 10:** 46/1.2/0393

**EPRAJUB 15:** 46/1.2/0394

**EPRAJUB 20:** 46/1.2/0395

## **10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Jubilant Pharma SA (Pty) Ltd

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**11. DATE OF PUBLICATION**

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