

## APPROVED PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** **S3**

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

**CELEBREX® 100 Capsules**

**CELEBREX® 200 Capsules**

### Read this leaflet carefully before you start taking CELEBREX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- CELEBREX has been prescribed for you personally and you should not share your medicines with other people. It may harm them, even if their symptoms are the same as yours.

### 1. WHAT CELEBREX CONTAINS:

Each capsule contains either 100 or 200 mg celecoxib. The other ingredients are gelatin, lactose monohydrate, sodium lauryl sulphate, povidone K30, croscarmellose sodium, magnesium stearate and the colouring agent titanium dioxide. The printing ink contains shellac and propylene glycol. The 100 mg capsule also contains FD&C brilliant blue and the 200 mg capsule contains yellow ferric oxide.

### 2. WHAT CELEBREX IS USED FOR:

CELEBREX treats pain, inflammation and fever and belongs to a group of medicines called specific cyclooxygenase 2 (COX-2) inhibitors.

CELEBREX is used in the treatment of inflammation and pain in osteoarthritis and rheumatoid arthritis. CELEBREX is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, primary dysmenorrhoea and helps to relieve the signs and symptoms of progressive stiffening of the spine known as ankylosing spondylitis.

Your body makes substances called prostaglandins. Some prostaglandins cause pain and swelling, whilst others help protect the stomach lining. CELEBREX works by reducing the amount of

prostaglandins which produce pain and swelling without reducing the protective prostaglandins in the stomach.

### **3. BEFORE YOU TAKE CELEBREX:**

If you are taking medicines on a regular basis, concomitant use of the CELEBREX may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

#### **Do not take CELEBREX:**

- If you have had an allergic reaction to any of the ingredients in CELEBREX
- If you have had an allergic reaction to a group of medicines called “sulphonamides” (e.g. some antibiotics used to treat infections)
- If you have had nasal polyps or severe nasal congestion, or an allergic reaction such as an itchy skin rash, swelling, or wheezing after taking aspirin or another anti-inflammatory medicine, including other cyclooxygenase 2 inhibitors
- If you have a stomach or duodenal ulcer, or bleeding in the stomach
- If you have severe liver or kidney disease
- If you have severe heart failure, high blood pressure or if you have had a stroke
- If you are about to have coronary artery bypass graft surgery
- If you are pregnant or it is possible that you could become pregnant
- If you are breastfeeding

#### **Take special care with CELEBREX:**

Some people will need special care from their doctors when they are taking CELEBREX. Make sure that your doctor knows before you start taking CELEBREX:

- If you have had an ulcer, bleeding or perforation of the gastrointestinal tract
- If you have liver or kidney disease
- If you have oedema (fluid retention)
- If you have or have had heart disease
- If you have high blood pressure
- If you suffer from diabetes
- If you have high cholesterol

- If you smoke
- If you could be dehydrated, for example by sickness or diarrhoea or the use of diuretics
- If you have an infection, as it may hide fever

**Driving and using machinery:**

If you feel dizzy or tired after taking CELEBREX, do not drive or use machinery until you are feeling normal again.

**Taking other medicines with CELEBREX:**

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Before you start taking CELEBREX, make sure your doctor knows if you are taking:

- Aspirin
- ACE inhibitors (used for high blood pressure and heart failure)
- Diuretics (used to treat fluid retention)
- Fluconazole (used to treat fungal infections)
- Lithium (used to treat depression)
- Warfarin (used to prevent blood from clotting)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat

**4. HOW TO TAKE CELEBREX:**

Do not share medicines prescribed for you with others.

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

If you accidentally take too many capsules, tell your doctor or pharmacist as soon as possible. Do not take a double dose to make up for forgotten individual doses.

Use the lowest effective dose for the shortest possible time.

The recommended dose for osteoarthritis is 200 mg taken as a single dose or as two divided doses.

The recommended dose for rheumatoid arthritis is 100 mg or 200 mg twice per day.

The recommended dose for pain following dental surgery is 100 mg or 200 mg twice per day.

The recommended dose for pain following an operation is 200 mg once daily.

The recommended dose for musculoskeletal pain is 200 mg twice daily.

The recommended dose for primary dysmenorrhoea is 400 mg initially, followed by an additional 200 mg on the first day if needed. On subsequent days, the recommended dose is 200 mg twice daily.

The recommended dose for ankylosing spondylitis is 200 mg daily, taken as a single dose or as 100 mg twice per day.

If you have liver problems, or you are over 65 years of age and weigh less than 50 kg, do not take more than 100 mg once daily for osteoarthritis and 200 mg per day for rheumatoid arthritis.

## **5. POSSIBLE SIDE EFFECTS:**

CELEBREX can have side effects. Not all side effects reported for CELEBREX are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

**CELEBREX may cause the following reactions. Stop taking the capsules and tell your doctor immediately**

- If you have cardiac symptoms such as shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm
- If you experience dizziness and headache
- If you have an allergic reaction such as skin rash, swelling of the face, wheezing or difficulty breathing
- If you have blistering or peeling of the skin
- If you have any sign of bleeding in the stomach or intestines, such as passing black or blood-stained bowel movements, or vomiting blood

**Common side effects which may affect more than 1 and 10 in every 100 people, are listed below:**

- Sleeping problems, dizziness
- Fluid build-up in the body, swollen ankles and legs
- Bronchitis, coughing, blocked nose, swollen sinuses, sore throat, chest infection
- Stomach ache, diarrhoea, indigestion, wind
- Skin rash
- Urinary infections

**Uncommon side effects which may affect more than 1 person in 1 000, are listed below:**

- Raised blood pressure, palpitations (awareness of your heartbeat), feeling short of breath, coughing
- Vomiting
- Allergic skin reaction, loss of hair
- Anaemia, bruising of the skin
- Anxiety, depression, tiredness, blurred vision, tinnitus (ringing in the ears)

**Rare side effects which may affect more than 1 person in 10 000, are listed below:**

- Fluid build-up in the tissues
- Feeling confused
- Congestive heart failure
- Ulcers in the digestive system, blood in bowel movements
- Effects on the skin such as bruising

**The following side effects have been reported in post-marketing surveillance:**

- Sudden, life threatening severe allergic reaction
- Hallucinations
- Inflammation of the blood vessels
- Bleeding in the digestive system
- Hepatitis (inflamed liver)
- Kidney failure or kidney disease
- Effects on the skin such as flushing, swelling, blistering and peeling or increased sensitivity to light
- Heart failure, blood clotting and stroke
- Absence of sense of smell and infection of the brain membranes
- Menstrual disorders

**6. STORING AND DISPOSING OF CELEBREX:**

Store all medicines out of reach of children.

Store your capsules at or below 25 °C.

Do not take the capsules after the expiry date shown on the blister and carton. If your capsules are out of date, take them to your pharmacist who will get rid of them safely.

## **7. PRESENTATION OF CELEBREX:**

CELEBREX is supplied in blister strips, each containing 10 or 15 capsules. The capsules are placed in an outer cardboard carton. The carton may contain 10, 15, 30 or 60 capsules.

## **8. IDENTIFICATION OF CELEBREX:**

CELEBREX 100 mg capsules are opaque, white to off-white, hard gelatin capsules with a blue band marked 7767 and 100, containing a white to off-white granulation.

CELEBREX 200 mg capsules are opaque, white to off-white, hard gelatine capsules with a gold band marked 7767 and 200, containing a white to off-white granulation.

## **9. REGISTRATION NUMBERS:**

CELEBREX 100: 33/3.1/0332

CELEBREX 200: 33/3.1/0333

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

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton, 2196

South Africa

## **11. DATE OF PUBLICATION:**

11 December 2008