

### 1.3.3 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S6**

#### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**TEMGESIC® 0,2 mg Sublingual Tablets**

**TEMGESIC® 1 ml (0,3 mg/ml) Injection**

**Active substance:** Buprenorphine (as hydrochloride)

#### Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist
- This medicine 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 TEMGESIC CONTAINS

Each TEMGESIC Sublingual Tablet contains 0,2 mg Buprenorphine (as hydrochloride). The other ingredients are citric acid anhydrous, magnesium stearate, maize starch, mannitol, povidone and sodium citrate.

Contains lactose monohydrate.

Each 1 ml of TEMGESIC Injection contains 0,3 mg Buprenorphine (as hydrochloride) in a 5 % dextrose solution.

#### WHAT TEMGESIC IS USED FOR

TEMGESIC contains buprenorphine, of the group of medicines called 'opioid analgesics'. It is a strong pain reliever that helps lessen moderate to severe pain.

## **BEFORE YOU USE TEMGESIC**

### **Do not use TEMGESIC Sublingual Tablets and Injection:**

- If you are allergic (hypersensitive) to buprenorphine or any of the other ingredients of TEMGESIC Sublingual Tablets and Injections or to other opioids (medicines that are morphine- like in their action)
- If you have serious problems with your liver
- If you have serious breathing problems.

### **Take special care with TEMGESIC Sublingual Tablets and Injection:**

- If you are or have ever been addicted to medicines or substances
- If you have problems with your liver
- If you have breathing problems or are taking medicines that may make your breathing slower or weaker
- Special care must be exercised in the elderly, where respiratory capacity may be reduced
- This product can cause sleepiness which may be increased by alcohol or anti-anxiety medicines.

Advise your doctor in case of:

- recent head injury or brain disease,
- decrease of blood pressure,
- in men: urinary disorders (especially linked to enlarged prostate).

Athletes must be aware that this medicine may cause a positive reaction to 'anti-doping' tests.

### **Using TEMGESIC with food and drink:**

Do not drink alcohol while you are taking TEMGESIC as it may make you feel drowsy.

### **Pregnancy and Breastfeeding:**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

The use of TEMGESIC is not recommended during pregnancy and for mothers who are breastfeeding.

**Driving and using machinery:**

TEMGESIC may cause drowsiness. If you feel tired, do not drive a motor vehicle or operate machinery.

**Important information about some of the ingredients of TEMGESIC:**

TEMGESIC contains lactose/dextrose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this product.

**Using other medicines with TEMGESIC Sublingual Tablets or Injection:**

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

(This includes complementary or traditional medicines.)

TEMGESIC should not be taken with:

- Medicines containing gestodene (a hormone)
- Antibiotic medicines (troleandomycin, rifampicin)
- Medicines to treat fungal infections (ketoconazole)
- Medicines for depression (norfluoxetine)
- Medicines for HIV infection (protease inhibitors: ritonavir, indinavir, saquinavir)
- Medicines for epilepsy (carbamazepine, phenytoin, phenobarbital)
- Other opioid medicines

In particular you should also tell your doctor if you are taking:

- Medicines used to treat depression known as monoamine oxidase inhibitors (examples include tranylcypromide, phenelzine)
- Medicines to help you sleep (e.g. tranquillizers, hypnotics or sedatives)

## **HOW TO USE TEMGESIC SUBLINGUAL TABLETS AND INJECTIONS**

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

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

The usual dose is 1 to 2 TEMGESIC tablets to be dissolved under the tongue every 6 to 8 hours or as required. The tablet may require 5 to 10 minutes to dissolve and should not be chewed or swallowed.

The usual dose of the TEMGESIC Injections is 0,3 to 0,6 mg into a muscle or slowly into a vein repeated every 6 to 8 hours or as required.

TEMGESIC Sublingual Tablets and Injections are not recommended for use in children.

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

### **If you use more TEMGESIC Sublingual Tablets or Injections than you should:**

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

The expected symptoms of an overdose are drowsiness, nausea, vomiting and respiratory depression (difficulty breathing).

### **If you forget to take TEMGESIC:**

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

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

Stopping treatment early may cause withdrawal symptoms.

If you have any further questions on the use of this product ask your doctor or pharmacist.

## POSSIBLE SIDE EFFECTS

TEMGESIC can cause side effects, although not everybody gets them.

**Tell your doctor immediately:** if you experience any of the following symptoms after taking TEMGESIC. You may need urgent medical attention or hospitalisation.

- If you get any sudden wheeziness, difficulty breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of an allergic reaction
- If you start to breathe more slowly or weakly than expected (respiratory depression)
- If you start to feel faint, as this may be a sign of low blood pressure

Other side-effects that may occur with TEMGESIC are:

- **Effects on your liver:** abnormal liver function; fever, loss of appetite, dark urine, yellowing of the eyes and skin.
- **Effects on your stomach or intestine:** feeling sick, being sick, diarrhoea.
- **Effects on your nervous system:** dizziness, hallucinations (sensing things that are not real), drowsiness, headaches, sweating, difficulty with balance and walking, tremor and impaired speech.
- **Effects on your bladder:** difficulty in urinating.
- **Effects on your eyes:** blurred vision.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

## STORING AND DISPOSING OF TEMGESIC

Store at or below 30 °C. Protect from light and moisture.

Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **PRESENTATION OF TEMGESIC**

TEMGESIC Sublingual Tablets:

Carton of 50 tablets, containing blister strips of 10 tablets each.

TEMGESIC 1 ml Injection:

A colourless solution in clear glass ampoules of 1 ml in packs of 5 ampoules.

## **IDENTIFICATION OF TEMGESIC**

TEMGESIC Sublingual Tablets are white bi-convex tablets engraved on one side with the letter "L".

TEMGESIC 1 ml Injection is a colourless solution in clear glass ampoules of 1 ml.

## **REGISTRATION NUMBERS**

TEMGESIC Sublingual Tablets: S/2.7/327

TEMGESIC 1 ml Injection: L/2.9/157

## **NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:**

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road, Aeroton,

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## **DATE OF REGISTRATION**

TEMGESIC Sublingual Tablets: 11 December 1989

TEMGESIC 1 ml Injection: 18 April 1984

## **DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:**

24 October 2014

## **COUNTRY REGISTRATION NUMBERS**

TEMGESIC Sublingual Tablets; Botswana: BOT0400660 S2

TEMGESIC 1 ml Injection; Botswana: BOT0400659 S2