1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S6**

SUBUTEX SUBLINGUAL 0,4 mg tablets

SUBUTEX SUBLINGUAL 2 mg tablets

SUBUTEX SUBLINGUAL 8 mg tablets

The active substance is buprenorphine.

Contains sugar:

Each 0,4 mg tablet contains 26,626 mg lactose monohydrate and 18,0 mg mannitol.

Each 2 mg tablet contains 47,94 mg lactose monohydrate and 30,0 mg mannitol.

Each 8 mg tablet contains 191,76 mg lactose monohydrate and 120,0 mg mannitol.

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, pharmacist, nurse or other health care provider.
- 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 is in this leaflet

This medicine contains buprenorphine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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1. What SUBUTEX is and what it is used for

SUBUTEX SUBLINGUAL tablets are used as a part of a medical, social and psychological treatment programme for patients addicted to opiate (narcotic) drugs.

This medicine contains buprenorphine which belongs to a class of medicines called opioids.
This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take SUBUTEX SUBLINGUAL

Do not take SUBUTEX SUBLINGUAL

- If you are a child under the age of 15 years.
- If you are allergic to buprenorphine or any of the other ingredients in this medicine.
- If you have serious breathing problems.
- If you have serious problems with your liver, or if your doctor detects the development of such problem during treatment.
- If you are intoxicated due to alcohol or have delirium tremens (the ·'shakes' and hallucinations).

Warnings and precautions

Tell your doctor if you have any of the following illnesses before treatment or develop them during treatment, as your doctor may need to reduce your dose of this medicine or you may need extra treatment to control them:

- Seizures, fits or convulsions
- Asthma or other breathing problems
- Kidney disease
- Liver disease

- Depression or other conditions that are treated with antidepressants. The use of these medicines together with SUBUTEX SUBLINGUAL can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and SUBUTEX SUBLINGUAL”).

SUBUTEX SUBLINGUAL should be used exactly as prescribed by your doctor. Some people have died from respiratory failure (inability to breathe) because they misused buprenorphine or whilst using Central Nervous System depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.
Therefore, whilst you are being treated with this medicine, do not use benzodiazepines (medicines used to treat anxiety or sleep disorders) unless they have been prescribed by your doctor.

Taking this medicine regularly, particularly for a long time, can lead to addiction.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

This medicine can cause withdrawal symptoms if you take it less than four hours after you use a narcotic (morphine, heroin or other related products).

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else.
Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Cases of acute hepatic injury (liver problems) have been reported in a context of misuse, especially by intravenous route and at high dose. These injuries could be due to special conditions as viral

infections (chronic C hepatitis), alcohol abuse, anorexia, or medicines association (for example: antiretroviral nucleoside analogues, isoniazid, valproate). If you have symptoms of severe fatigue, itching, or if your skin or eyes look yellow, tell your doctor immediately, so that you can receive the proper treatment.

SUBUTEX SUBLINGUAL may cause your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down.
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).

SUBUTEX SUBLINGUAL can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Athlete's should be aware that taking this medicine may cause a positive reaction to "anti-doping" tests.

Other medicines and SUBUTEX SUBLINGUAL
Always tell your health care [professional] provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

You should not use benzodiazepines (medicines used to treat anxiety or sleep disorders) whilst you are taking SUBUTEX SUBLINGUAL unless they are prescribed by your doctor.

Concomitant use of SUBUTEX SUBLINGUAL and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression),

coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However, if your doctor does prescribe SUBUTEX SUBLINGUAL together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Strong pain killers and cough medicines containing opioid-related substances, certain anti-depressants, including monoamine oxidase inhibitors, sedating antihistamines, sedatives, anti-anxiety drugs, certain drugs for high-blood pressure and antipsychotic drugs may increase the effects of SUBUTEX SUBLINGUAL.

Anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with SUBUTEX SUBLINGUAL and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that
control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38 °C. Contact your doctor when experiencing such symptoms.

Ketoconazole, a medicine used for the treatment of fungal infections, can increase the effects of SUBUTEX SUBLINGUAL if both are taken at the same time. If you are taking ketoconazole or any of the following medicines: macrolide antibiotics e.g., troleandomycin, gestodene the HIV protease inhibitor ritonivir, indinavir, and saquinavir, you should tell your doctor or pharmacist, as they need to reduce your dose of SUBUTEX SUBLINGUAL.

Also tell your doctor or pharmacist if you are taking any of the following medicines: phenobarbital, carbamazepine, phenytoin, rifampicin. You will be closely monitored whilst you are taking these medicines at the same time as SUBUTEX SUBLINGUAL.

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Be sure to tell your doctor if you are taking a blood thinning drug called phenprocoumon.

If you are taking any other medicines, you should tell your doctor or pharmacist before you begin treatment with SUBUTEX SUBLINGUAL.

SUBUTEX SUBLINGUAL with food, drink and alcohol

Do not drink alcohol or take medicines that contain alcohol whilst you are being treated with SUBUTEX SUBLINGUAL. Alcohol and certain other medicines (as listed under 'Other medicines with SUBUTEX SUBLINGUAL') increases the sedative effects of buprenorphine, which can make driving and operating machinery hazardous.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take SUBUTEX SUBLINGUAL if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use SUBUTEX SUBLINGUAL during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take SUBUTEX SUBLINGUAL while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

Driving and using machines

This medicine can cause drowsiness, which may be made worse if you also drink alcohol or take tranquillisers or anti-anxiety drugs. If you are drowsy, do not drive or operate machinery.

SUBUTEX SUBLINGUAL contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take SUBUTEX SUBLINGUAL

Do not share medicines prescribed for you with any other person.
Always take SUBUTEX SUBLINGUAL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

SUBUTEX SUBLINGUAL tablets are administered sublingually. This means that you must place the tablet under your tongue and allow to dissolve, which will take 5 to 10 minutes. This is the only way the tablets should be taken. Do not chew or swallow them whole, as this will make them ineffective. Your doctor will tell you how much SUBUTEX SUBLINGUAL to take and you should always follow his advice.

Adults and children over the age of 15 years: the initial dose is from 0,8 mg to 4 mg, administered once a day.
For drug addicts who have not undergone withdrawal: one dose of SUBUTEX SUBLINGUAL tablets at least 4 hours after the last use of the opiod (narcotic), or when the first signs of craving appear.
For patients receiving methadone: before beginning treatment, your doctor should reduce your dose of methadone to a maximum of 30 mg a day. SUBUTEX SUBLINGUAL may cause withdrawal symptoms in patients who are dependent on methadone.

During your treatment your doctor may increase your dose of SUBUTEX SUBLINGUAL to a maximum single daily dose of 16 mg, depending upon your response. After a period of successful treatment,

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your doctor may gradually reduce your dose. Depending on your condition, your dose may continue to be reduced under careful medical supervision, until it is stopped altogether. Do not suddenly stop taking the tablets, as this may cause withdrawal symptoms.

Your prescriber should discuss your treatment and whether you need to continue taking tablets at regular intervals. If you and your prescriber decide to stop treatment, a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimise the risk of withdrawal effects.

If you take more SUBUTEX SUBLINGUAL than you should

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

If you forget to take SUBUTEX SUBLINGUAL

You should tell your doctor and follow his or her instructions.

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

If you stop taking SUBUTEX SUBLINGUAL

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

4. Possible side effects

SUBUTEX SUBLINGUAL can have side effects.

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 taking this medicine, please consult your doctor, pharmacist or other health care provider for advice.

After your first dose, you may suffer from some opiate withdrawal symptoms. Other side-effects which may occur are:

- constipation
- headaches
- difficulty in sleeping
- lack of energy or weakness
- drowsiness
- nausea and vomiting
- fainting and dizziness
- drop in blood pressure on changing position from sitting or lying down to standing
- sweating.

Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems (see 'Warnings and Precautions').

Common side effects (occurring in at least 1 in 100 patients) that may occur during treatment with SUBUTEX SUBLINGUAL are: weight loss, swelling (hands and feet), tiredness, drowsiness, anxiety, nervousness, tingling, depression, decreased sexual drive, muscle spasms, abnormal thinking, tearing disorder, blurred vision, flushing, increased blood pressure, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach, diarrhoea, abnormal liver function, loss of appetite, flatulence, vomiting, rash, itching, hives, pain, joint pain, muscle pain, leg cramps, impotence, urine abnormality, abdominal pain, back pain, weakness, infection, chills, chest pain, fever, flu syndrome, feeling of general discomfort, accidental injury, faintness and dizziness, drop in blood pressure on changing position from sitting or lying down to standing.

Uncommon side-effects (occurring in at least 1 in 1,000 patients) with SUBUTEX SUBLINGUAL are: swollen glands (lymph nodes), blood abnormalities, agitation, tremor, abnormal dreams, excessive muscle activity, depersonalisation (not feeling like yourself), medicine dependence, amnesia (memory disturbance), loss of interest, exaggerated feeling of wellbeing, convulsion (fits), speech disorder, small pupil size, problems with urination, conjunctivitis, rapid or slow heartbeat, low blood

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pressure, palpitations, myocardial infarction (heart attack), shortness of breath, asthma, yawning, pain and sores in mouth, tongue discolouration, acne, skin nodule, hair loss, dry or scaling skin, inflammation of joints, urinary tract infection, blood in urine, abnormal ejaculation, menstrual or vaginal problems, kidney stone, sensitivity to heat or cold, allergic reactions, feelings of hostility.

Drug dependence, addiction and seizures can occur as a result of taking this medicine.

Drug withdrawal

When you stop taking SUBUTEX SUBLINGUAL, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

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 SUBUTEX SUBLINGUAL.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store SUBUTEX SUBLINGUAL

Keep all medicines out of the reach and sight of children.

Store at or below 30°C in a dry place (not in a bathroom), in the original container.

Do not use this product after the expiry date that appears on the package. 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

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What SUBUTEX SUBLINGUAL contains

The active substance is:

SUBUTEX SUBLINGUAL 0,4 mg tablets:

Each tablet contains: Buprenorphine hydrochloride equivalent to 0,4 mg buprenorphine base.

SUBUTEX SUBLINGUAL 2 mg tablets:

Each tablet contains: Buprenorphine hydrochloride equivalent to 2,0 mg buprenorphine base.

SUBUTEX SUBLINGUAL 8 mg tablets:

Each tablet contains: Buprenorphine hydrochloride equivalent to 8,0 mg buprenorphine base.

The other ingredients are:

Lactose monohydrate, mannitol, maize starch, povidone, citric acid, sodium citrate and magnesium stearate.

What SUBUTEX SUBLINGUAL looks like and contents of the pack

SUBUTEX SUBLINGUAL 0,4 mg tablets:

Oval, flat, glossy, white to creamy-white tablet with “04” on the one side.

SUBUTEX SUBLINGUAL 2 mg tablets:

Oval, flat, glossy, white to creamy-white tablet with “B2” on the one side.

SUBUTEX SUBLINGUAL 8 mg tablets:

Oval, flat, glossy, white to creamy-white tablet with “B8” on the one side.

SUBUTEX SUBLINGUAL is packed in blister strips of 7 tablets. The packs contain either 7 or 28 tablets per carton.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd

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This leaflet was last revised in

Date of registration: 15 November 2002

Date of revision of text: 27 July 2022

Registration numbers

SUBUTEX SUBLINGUAL 0,4 mg: 33/34/0377

SUBUTEX SUBLINGUAL 2 mg: 33/34/0378

SUBUTEX SUBLINGUAL 8 mg: 33/34/0379

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