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PACKAGE LEAFLET:
INFORMATION FOR THE USER
Subutex® 0.4 mg, 2 mg and 8 mg
sublingual tablets
buprenorphine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Subutex is and what it is used for
2. What you need to know before you take Subutex
3. How to take Subutex
4. Possible side effects
5. How to store Subutex
6. Contents of the pack and other information

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

1. WHAT SUBUTEX IS AND WHAT IT IS USED FOR

Subutex is used to treat dependence on opiate (narcotic) drugs, such as morphine and heroin in drug addicts who have agreed to be treated for their addiction.
Subutex is used in adults and adolescents over 16 years of age who are also receiving medical, social and psychological support.
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

Do not take Subutex:
- If you are a child under the age of 16 years.
- If you are allergic to buprenorphine or any of the other ingredients of this medicine (listed in section 6).
- If you have **serious breathing problems**.
- If you have **serious problems with your liver**.
- If you are intoxicated due to alcohol or have trembling, sweating, anxiety confusion or hallucinations caused by alcohol.
- If you are breast feeding a baby.

Warnings and precautions
Talk to your doctor before taking Subutex if you have:
- seizures, fits or convulsions
- asthma or other breathing problems
- any liver disease such as hepatitis
- low blood pressure
- recently suffered head injury or brain disease
- a urinary disorder (especially linked to enlarged prostate in men)
- any kidney disease
- thyroid problems
- adrenocortical disorder (e.g. Addison's disease)
- depression or other conditions that are treated with antidepressants. The use of these medicines together with Subutex can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Subutex").

Important things to be aware of:
- **Misuse, abuse and diversion**
  This medicine can be a target for people who abuse prescription medicines, and should be kept in a safe place to protect it from theft. 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.
- **Breathing problems**
  Some people have died from respiratory failure (inability to breathe) because they misused this medicine or took it in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids.

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Pharmacode Reads This Way
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First Bar
8 mm

Tolerance, dependence and addiction
This medicine contains buprenorphine which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of buprenorphine can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose.
Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it.
The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent on or addicted to buprenorphine if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking buprenorphine, it could be a sign that you have become dependent or addicted:
- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop using Subutex).
- **Addiction and withdrawal symptoms**
  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 product can cause withdrawal symptoms if you take it less than 6 hours after you use a short-acting opioid (e.g. morphine, heroin) or less than 24 hours after you use a long-acting opioid such as methadone.
- **Liver damage**
  Liver damage has been reported after taking Subutex, especially when the medicine is misused. This could also be due to viral infections (chronic hepatitis C), alcohol abuse, anorexia or use of other medicines with the ability to harm your liver (see section 4). **Regular blood tests may be conducted by your doctor to monitor the condition of your liver. Tell your doctor if you have any liver problems before you start treatment with Subutex**.
- **Blood pressure**
  This product may cause your blood pressure to drop suddenly, causing you to feel dizzy if you get up too quickly from sitting or lying down.
- **Diagnosis of unrelated medical conditions**
  This medicine may mask pain symptoms that could assist in the diagnosis of some diseases. Do not forget to advise your doctor if you take this medicine.

Other medicines and Subutex
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines may increase the side effects of Subutex and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Subutex without first talking to your doctor, especially:
- Benzodiazepines (used to treat anxiety or sleep disorders) such as diazepam, temazepam, alprazolam. Concomitant use of Subutex and sedative medicines such as benzodiazepines or related drugs 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 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.
- Gabapentin or pregabalin to treat epilepsy or pain due to nerve problems (neuropathic pain).
- Anti-depressants, such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Subutex 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.
- **Other medicines that may make you feel sleepy** which are used to treat illnesses such as anxiety, sleeplessness, convulsions / seizures, pain. These types of medicines will reduce your alertness levels making it difficult for you to drive and use machines. They may also cause central nervous system depression, which is very serious. Below is a list of examples of these types of medicines:
  - other opioid containing medicines such as methadone, certain pain killers and cough suppressants.
  - antidepressants (used to treat depression) such as isocarboxazide, phenelzine, selegeline, tranylcypromine, and valproate may increase the effects of this medicine.
  - sedative H_1 receptor antagonists (used to treat allergic reactions) such as diphenhydramine and chlorphenamine.
  - barbiturates (used to cause sleep or sedation) such as phenobarbital, secobarbital.
  - tranquilisers (used to cause sleep or sedation) such as chloral hydrate.
- Naltrexone may prevent Subutex from working. If you take naltrexone whilst you are taking Subutex you may experience a sudden onset of prolonged and intense withdrawal symptoms.
- Clonidine (used to treat high blood pressure) may extend the effects of this medicine.
- Anti-retrovirals (used to treat AIDS) such as ritonavir, nelfinavir, indinavir may increase the effects of this medicine.
- Some antifungal agents (used to treat fungal infections) such as ketoconazole and itraconazole and certain antibiotics (macrolide) may extend the effects of this medicine.
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics);
- medicines to treat psychiatric disorders (antipsychotics or neuroleptics);
- muscle relaxants;
- medicines to treat Parkinson's disease.
- Some medicines may decrease the effect of Subutex. These include medicines used to treat epilepsy (such as carbamazepine and phenytoin) and medicines used to treat tuberculosis (rifampicin).

To get the greatest benefit from taking Subutex, you must tell your doctor about all the medicines you are taking, including alcohol, medicines containing alcohol, street drugs, and any prescription medicine you are taking that has not been prescribed for you by your doctor.

Subutex with food, drink and alcohol
Alcohol may increase drowsiness and may increase the risk of respiratory failure (inability to breathe) if taken with Subutex. **Do not take Subutex together with alcohol**. Do not swallow or consume food or drink until the tablet is completely dissolved.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take Subutex 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.

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If you use Subutex during pregnancy, your baby may become dependent and experience withdrawal symptoms including problems with breathing after the birth which may need to be treated. These symptoms may occur several days after birth.
Do not take Subutex while you are breastfeeding as buprenorphine passes into breast milk and will affect your baby.

Driving and using machines
If you feel drowsy or dizzy while taking these tablets do not use machinery.
The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Subutex contains lactose and sodium
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. HOW TO TAKE SUBUTEX

You must place the tablet under your tongue (sublingual) and allow it to dissolve, which will take 5 to 10 minutes. This is the only way to take the tablets. Do not chew or swallow them whole, as they will not work.
Your doctor will tell you how many tablets to take and you should always follow this advice.
To avoid sudden withdrawal symptoms, treatment with Subutex should be given when there are already clear signs of 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.

Adults and children over the age of 16 years: when beginning treatment the dose is between 0.8 to 4mg, taken once a day.

For drug addicts who have not had any withdrawal treatment: one dose of Subutex should be taken at least 6 hours after the last use of the opioid (narcotic such as morphine or heroin), or when the first signs of craving appear. If you take it less than six hours after you use a narcotic you may get withdrawal symptoms.

For patients taking methadone: before beginning treatment, your doctor should reduce your dose of methadone to not more than 30mg a day. Subutex may cause withdrawal symptoms in patients who are dependent on methadone if used within 24 hours of the last dose of methadone.

37.5 mm | 37.5 mm | 37.5 mm | 37.5 mm | 37.5 mm | 37.5 mm | 37.5 mm | 37.5 mm

300 mm

22 mm

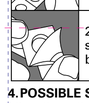
During your treatment, your doctor may increase your dose of Subutex, to a maximum single daily dose of 32mg, depending upon your response. Once you have been stable for a while, your doctor will gradually reduce your dose and it may be possible to stop it altogether. Do not suddenly stop taking the tablets, as this may cause withdrawal symptoms.

If you take more Subutex than you should
If you or someone else takes too much of this medicine, you must go or be taken immediately to an emergency centre or hospital as overdose with Subutex may cause serious and life-threatening breathing problems.

If you forget to take Subutex
Tell your doctor as soon as possible if you miss a dose and follow his or her instructions. Do not take a double dose to make up for the forgotten dose.

If you stop taking Subutex
Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you. 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.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

How to remove the tablet from the blister pack

	1 – Remove just one section from the blister pack, tearing it along the perforated line.
	2 – Starting from the edge where the seal is lifted, pull back the foil on the back to remove the tablet.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Tell your doctor immediately or seek urgent medical attention if you experience side effects such as:
- sudden wheezing, difficulty breathing, swelling of the eyelids, face, tongue, lips, throat or hands; rash or itching especially those covering your whole body. These may be signs of a life-threatening 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.

Also tell your doctor immediately if you experience side effects such as:
- severe fatigue (tiredness), have no appetite or if your skin or eyes look yellow. These may be symptoms of liver damage.

The frequency of possible side effects listed below is defined using the following convention:
- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- not known (frequency cannot be estimated from the available data).

Drug Withdrawal

Side effects reported with Subutex
Very common side effects:
Drug withdrawal syndrome, headache, hyperhidrosis (sweating), insomnia (inability to sleep), nausea (feeling sick), pain
Common side effects:
Abdominal pain, agitation, anxiety, joint pain, weakness, back pain, bone pain, bronchitis, chest pain, chills, constipation, cough, decreased appetite, depression, diarrhoea, dizziness, dry mouth, painful period, indigestion, shortness of breath, flatulence, gastrointestinal disorder, hostility, increase in muscle tension, infection, influenza, nervousness, tearing (watery eyes) disorder, swollen glands (lymph nodes), malaise, migraine, muscle spasms, muscle pain, dilation of the pupil, neck pain, palpitations, paranoia, burning or tingling in hands and feet, swelling (hands and feet), runny or stuffy nose, sore throat and painful swallowing, fever, rash, somnolence, syncope (fainting), thinking abnormal, tooth disorder, tremor, flushing, vomiting (being sick), yawning
Frequency not known:
Dental caries, drug dependence and addiction, seizures, drug withdrawal syndrome in newborn, hallucinations (sensing things that are not real), drop in blood pressure on changing position from sitting or lying down to standing, difficulty in urinating, vertigo Misusing this medicine by injecting it can cause withdrawal symptoms, infections, other skin reactions and potentially serious liver problems

When you stop taking Subutex, 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.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SUBUTEX

Keep out of the sight and reach of children.
Store this medicine in a safe and secure place, where other people cannot access it. It can cause serious harm and be fatal to people who may take this medicine by accident, or intentionally when it has not been prescribed for them.
Do not store above 30°C.
Store in the original package.
Do not use this medicine after the expiry date which is stated on the carton after EXP.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Subutex contains
The active substance is buprenorphine (as buprenorphine hydrochloride).
Each sublingual tablet contains 0.4mg, 2mg or 8mg of buprenorphine.
The other ingredients are monohydrated lactose, mannitol, maize starch, povidone K30, citric acid, magnesium stearate and sodium citrate.

What Subutex looks like and contents of the pack
Subutex 0.4mg sublingual tablets are uncoated oval white tablets of 8 mm x 4 mm, debossed with "04" on one side.
Subutex 2mg sublingual tablets are uncoated oval white tablets of 10 mm x 5 mm, debossed with "B2" on one side.
Subutex 8mg sublingual tablets are uncoated oval white tablets of 14 mm x 7 mm, debossed with "B8" on one side.
The sublingual tablets come in blister packs containing either 7 or 28 tablets.

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Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Indivior UK Limited
The Chapleo Building
Henry Boot Way
Priory Park, Hull
HU4 7DY
UK

Manufacturer:
Reckitt Benckiser Healthcare (UK) Limited
Dansom Lane
Hull, HU8 7DS
UK

For any information about this medicine, please contact the Marketing Authorisation Holder:
Indivior UK Limited
Telephone 0808 234 9243
PatientSafetyRoW@indivior.com

This leaflet was last revised in

SM01656

22 mm

150 mm | 170 mm | 170 mm

CUSTOMER INFO:
Minimum Point Size =10.00pt

Indivior Artwork and Print Specification

Trident Reference No:	TRIND638680
ZEN Ref:	**TR3401001**
Action:	**A**
Brand:	Buprenorphine
Category:	Treatment
Segment Group:	Subutex
Segment:	0.4mg, 2mg & 8mg
Pack Size:	N/A -
Market/Country:	UK
Date:	18/12/2024
RBH Contact:	Sam Norman

Artwork Type: Submission

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Parent Technical Packaging Specification:	D0374542
Supplier Code:	**000000**
Supply Point:	RB
Pharmacode No/NE:	101011011 428
Edgemark Position:	N/A
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Substrate:	Paper White

Technical & Non Printing Items
Dieline | Dieline 2 (if applicable)
Guides | Guides 2 (if applicable)

Colours
Black

BARCODE INFO

Barcode Type:	PHARMACODE STANDARD
Barcode Number:	428
Magnification:	100%
Full Height:	N/A
Bar Height (Smallest Bar)	8
BWR:	N/A

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TRIDENT
Connaught House, Connaught Road,
Kingswood Business Park, Hull, HU7 3AP, England.
T: +44 (0) 1482 828100

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