

PACKAGE LEAFLET: INFORMATION FOR THE USER

SUBUTEX® 2mg SUBLINGUAL TABLETS**SUBUTEX® 8mg SUBLINGUAL TABLETS**

(buprenorphine hydrochloride)

Your medicine is called Subutex 2mg Sublingual Tablets and Subutex 8mg Sublingual Tablets but will be referred to as Subutex throughout the remainder of the leaflet.

Information regarding other strength Subutex 0.4mg Sublingual Tablets is also present in the below leaflet.

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.

• **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.
- 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, selegiline, tranylcypromine, and valproate may increase the effects of this medicine.
 - sedative H₁ 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.
- 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. 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:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - 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.

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

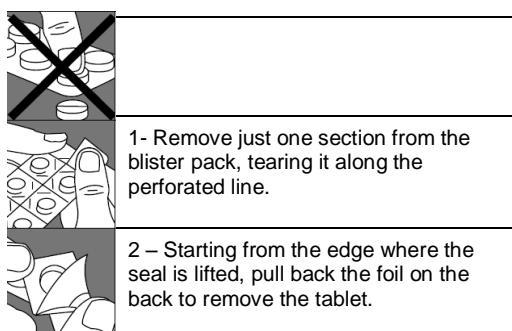
Tell your doctor as soon as possible if you miss a dose and follow his or her instructions. Do not take a double dose to make up for the forgotten dose.

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



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).

Side effects reported with Subutex
<i>Very common side effects:</i>
Drug withdrawal syndrome, headache, hyperhidrosis (sweating), insomnia (inability to sleep), nausea (feeling sick), pain
<i>Common side effects:</i>
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
<i>Frequency not known:</i>
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

Drug Withdrawal

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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.**
- Subutex should not be stored above 30°C. They should be stored in the original package.
- Do not use after the expiry date printed on the carton label or blister strip.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Subutex contains

- Each Subutex Sublingual 2mg Tablets contains 2.16mg buprenorphine hydrochloride equivalent to 2mg buprenorphine.
- Each Subutex 8mg Sublingual Tablets contain 8.64mg buprenorphine hydrochloride equivalent to 8mg buprenorphine.
- Subutex Sublingual Tablets also contain the following inactive ingredient: lactose monohydrate, mannitol (E421), maize starch, povidone K30, citric acid, sodium citrate and magnesium stearate.

What Subutex looks like and contents of the pack

- Subutex Sublingual 2mg Tablets are oval white tablets marked 'B2' on one side with a sword logo on the other.
- Subutex Sublingual Tablets are oval white tablets marked 'B8' on one side with a sword logo on the other.
- Subutex Sublingual Tablets are available as blister packs of 7 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Parallel Import Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by Reckitt Benckiser Healthcare (UK) Ltd., Dansom Lane, Hull, HU8 7DS, United Kingdom.

POM

PL: 19488/0514 Subutex 2mg Sublingual Tablets
PL: 19488/0515 Subutex 8mg Sublingual Tablets



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PACKAGE LEAFLET: INFORMATION FOR THE USER

BUPRENORPHINE 2mg SUBLINGUAL TABLETS
BUPRENORPHINE 8mg SUBLINGUAL TABLETS
 (buprenorphine hydrochloride)

Your medicine is called Buprenorphine 2mg Sublingual Tablets and Buprenorphine 8mg Sublingual Tablets but will be referred to as Buprenorphine Sublingual Tablets throughout the remainder of the leaflet.

Information regarding other strength Buprenorphine 0.4mg Sublingual Tablets is also present in the below leaflet.

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 Buprenorphine Sublingual Tablets are and what they are used for
2. What you need to know before you take Buprenorphine Sublingual Tablets
3. How to take Buprenorphine Sublingual Tablets
4. Possible side effects
5. How to store Buprenorphine Sublingual Tablets
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 BUPRENORPHINE SUBLINGUAL TABLETS ARE AND WHAT THEY ARE USED FOR

Buprenorphine Sublingual Tablets are 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.

Buprenorphine Sublingual Tablets are used in adults and adolescents over 16 years of age who are also receiving medical, social and psychological support.

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 BUPRENORPHINE SUBLINGUAL TABLETS

Do not take Buprenorphine Sublingual Tablets:

- 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 Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Buprenorphine Sublingual Tablets").

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.

• **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 Buprenorphine Sublingual Tablets, 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 Buprenorphine Sublingual Tablets.**

• **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 Buprenorphine Sublingual Tablets

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 Buprenorphine Sublingual Tablets and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Buprenorphine Sublingual Tablets without first talking to your doctor, especially:

- Benzodiazepines (used to treat anxiety or sleep disorders) such as diazepam, temazepam, alprazolam. Concomitant use of Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets 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.
- Anti-depressants, such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Buprenorphine Sublingual Tablets 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, selegiline, tranylcypromine, and valproate may increase the effects of this medicine.
 - sedative H₁ 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 Buprenorphine Sublingual Tablets from working. If you take naltrexone whilst you are taking Buprenorphine Sublingual Tablets 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.
- Some medicines may decrease the effect of Buprenorphine Sublingual Tablets. 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 Buprenorphine Sublingual Tablets, 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.

Buprenorphine Sublingual Tablets with food, drink and alcohol

Alcohol may increase drowsiness and may increase the risk of respiratory failure (inability to breathe) if taken with Buprenorphine Sublingual Tablets. **Do not take Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets 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:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - 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.

Buprenorphine Sublingual Tablets 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 BUPRENORPHINE SUBLINGUAL TABLETS

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 Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets 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. Buprenorphine Sublingual Tablets may cause withdrawal symptoms in patients who are dependent on methadone if used within 24 hours of the last dose of methadone.

During your treatment, your doctor may increase your dose of Buprenorphine Sublingual Tablets, 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 Buprenorphine Sublingual Tablets 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 Buprenorphine Sublingual Tablets may cause serious and life-threatening breathing problems.

If you forget to take Buprenorphine Sublingual Tablets

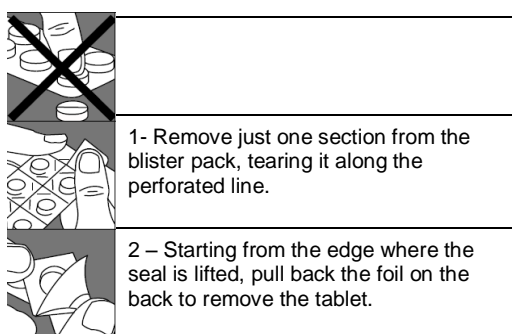
Tell your doctor as soon as possible if you miss a dose and follow his or her instructions. Do not take a double dose to make up for the forgotten dose.

If you stop taking Buprenorphine Sublingual Tablets

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



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).

Side effects reported with Buprenorphine Sublingual Tablets
<i>Very common side effects:</i>
Drug withdrawal syndrome, headache, hyperhidrosis (sweating), insomnia (inability to sleep), nausea (feeling sick), pain
<i>Common side effects:</i>
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
<i>Frequency not known:</i>
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

Drug Withdrawal

When you stop taking Buprenorphine Sublingual Tablets, 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 BUPRENORPHINE SUBLINGUAL TABLETS

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Buprenorphine Sublingual Tablets should not be stored above 30°C. They should be stored in the original package.
- Do not use after the expiry date printed on the carton label or blister strip.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Buprenorphine Sublingual Tablets contain

- Each Buprenorphine Sublingual 2mg Tablets contains 2.16mg buprenorphine hydrochloride equivalent to 2mg buprenorphine.
- Each Buprenorphine 8mg Sublingual Tablets contain 8.64mg buprenorphine hydrochloride equivalent to 8mg buprenorphine.
- Buprenorphine Sublingual Tablets also contain the following inactive ingredient: lactose monohydrate, mannitol (E421), maize starch, povidone K30, citric acid, sodium citrate and magnesium stearate.

What Buprenorphine Sublingual Tablets look like and contents of the pack

- Buprenorphine Sublingual 2mg Tablets are oval white tablets marked 'B2' on one side with a sword logo on the other.
- Buprenorphine Sublingual Tablets are oval white tablets marked 'B8' on one side with a sword logo on the other.
- Buprenorphine Sublingual Tablets are available as blister packs of 7 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Parallel Import Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by Reckitt Benckiser Healthcare (UK) Ltd., Dansom Lane, Hull, HU8 7DS, United Kingdom.

POM PL: 19488/0514 Buprenorphine 2mg Sublingual Tablets
PL: 19488/0515 Buprenorphine 8mg Sublingual Tablets



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