

PACKAGE LEAFLET: INFORMATION FOR THE USER

Subutex

0.4mg, 2mg and 8mg Sublingual Tablets
Buprenorphine 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 any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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.

In this leaflet:

1. What Subutex is and what it is used for
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1. WHAT SUBUTEX IS AND WHAT IT IS USED FOR

Subutex Sublingual Tablets contain buprenorphine hydrochloride, which is a medicine called an 'opioid analgesic'. These medicines are strong pain killers but Subutex is used to help patients addicted to opiate (narcotic) drugs, such as morphine and heroin by acting as a substitute for these drugs. Over a period of time patients can withdraw from the narcotics that they were addicted to.

2. BEFORE YOU TAKE SUBUTEX SUBLINGUAL TABLETS

Do not take Subutex

If you are a child under the age of 15 years. If you are allergic to buprenorphine or to any of the other ingredients in this medicine. If you have serious breathing problems or are having an acute asthma attack. If you have serious problems with your liver. If you are intoxicated due to alcohol or have delirium tremens (the 'shakes' and hallucinations). If you have recently had a head injury or have a condition that causes pressure to build up in your head. If you are breast feeding a baby.

Take special care with Subutex

If you have:

- asthma or other breathing problems
- problems with your kidneys or liver
- low blood pressure
- an enlarged prostate gland or have difficulty when passing urine

Tell your doctor before taking Subutex.

Taking other medicines

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

Subutex may make you feel sleepy and taking any of the following medicines may make this worse. Tell your doctor if you are already taking:

- strong pain killers and cough medicines that contain opioid-related substances
- antidepressants, including monoamine oxidase inhibitors
- antihistamines that make you feel drowsy
- sedatives (to help you sleep)
- medicines for anxiety
- medicines for high blood pressure
- treatment for a mental problem.

You should tell your doctor if you are taking any of the following medicines as he may need to give you a lower dose of Subutex:

- Ketoconazole (a medicine used to treat fungal infections which can increase the levels of Subutex in your blood if both are taken at the same time)
- gestodene (found in contraceptives)
- troleandomycin (an antibiotic)
- ritonavir, indinavir and saquinavir (the HIV protease inhibitors)

Also tell your doctor or pharmacist if you are taking any of the following medicines:

- phenobarbital, carbamazepine or phenytoin (used in treatment of epilepsy)
- rifampicin (used for infections)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Subutex with food and drink

Do not drink alcohol or take medicines that contain alcohol whilst you are being treated with Subutex.

Pregnancy and breast-feeding

You should not take Subutex if you are pregnant unless your doctor has told you to. You must not breast-feed your baby if you are taking Subutex.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Important information about some of the ingredients of Subutex

Subutex Sublingual Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Athletes should be aware that this medicine may cause a positive reaction to “anti-doping” tests.

3. HOW TO TAKE SUBUTEX 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. Adults and children over the age of 15 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 you take it less than 24 hours after you use 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

Get medical help at once.

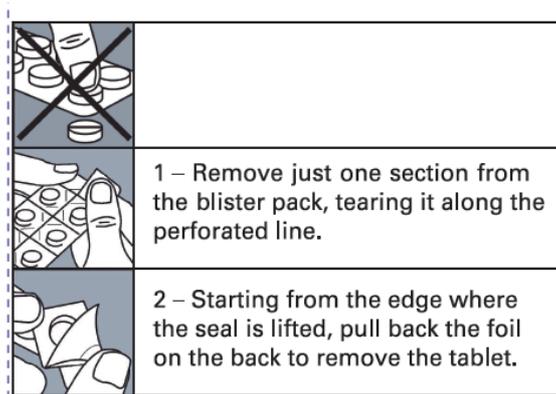
If you forget to take Subutex

You should tell your doctor 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 suddenly stop taking the tablets, as this may cause withdrawal symptoms.

How to remove the tablet from the blister pack



4. POSSIBLE SIDE EFFECTS

Like all medicines, Subutex can cause side effects, although not everybody gets them.

Hypersensitivity (allergic) reactions have been reported. Symptoms may include skin rash, hives and itching. If you develop symptoms of a severe allergic reaction (such as difficulty in breathing, wheezing, swelling to the eyes, lips, tongue, throat or hands) get medical help at once.

Some cases of liver problems have been reported during treatment, especially by intravenous route and at a high dose. These injuries could be due to conditions such as viral infections (chronic C hepatitis), alcohol abuse and anorexia. Liver problems may also occur when certain medicines are taken with Subutex such as antiretroviral nucleoside analogues, acetylsalicylic acid (aspirin), amiodarone, isoniazid and valproate. If you develop severe fatigue, have no appetite or if your skin or eyes look yellow, tell your doctor.

After your first dose, you may suffer from some opiate withdrawal symptoms. Other side effects could be constipation, headaches, difficulty in sleeping, lack of energy or feeling weak, drowsiness, feeling and being sick, sweating, fainting and dizziness, drop in blood pressure on changing position from sitting or lying down to standing. Some patients have reported hallucinations but these happen rarely.

It is possible that taking this medicine can lead to drug dependence.

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.

5. HOW TO STORE SUBUTEX SUBLINGUAL TABLETS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and foil. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package.

Do not use this medicine if you notice damaged blister pockets.

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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Subutex tablets contain

Subutex 0.4 mg sublingual tablets contain 0.4 mg buprenorphine (as hydrochloride). Subutex 2 mg sublingual tablets contain 2 mg buprenorphine (as hydrochloride). Subutex 8 mg sublingual tablets contain 8 mg buprenorphine (as hydrochloride).

The other ingredients are lactose monohydrate, mannitol (E421), maize starch, povidone K30, citric acid, magnesium stearate and sodium citrate.

What Subutex tablets look like and contents of the pack

Subutex 0.4 mg sublingual tablets are white, flat, oval tablets with 'sword' logo on one side and '04' on the other.

Subutex 2 mg sublingual tablets are white, oval tablets with 'Sword' logo on one side and 'B2' on the other.

Subutex 8 mg sublingual tablets are flat, oval tablets with 'Sword' logo on one side and 'B8' on the other.

The sublingual tablets come in nylon/aluminium/uPVC blister packs containing either 7 or 28 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

RB Pharmaceuticals Limited, 103-105 Bath Road, Slough, Berkshire SL1 3UH, UK.

Manufacturer responsible for batch release:

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

This leaflet was last approved in December 2011.