

BUPREN SUBLINGUAL TABLET

Buprenorphine (as hydrochloride) 8mg / Naloxone (as hydrochloride) 2mg
Buprenorphine (as hydrochloride) 2mg / Naloxone (as hydrochloride) 0.5mg

What is in this leaflet

1. What BUPREN is used for?
2. How BUPREN works
3. Before you use BUPREN
4. How to use BUPREN
5. While you are using BUPREN
6. Side effects
7. Storage and disposal of BUPREN
8. Product description
9. Manufacturer and product registration Holder
10. Date of revision

What BUPREN is used for?

Medicinal product used in opioid dependence. BUPREN is part of a medical, social and psychological treatment program for patients addicted to opiate (narcotic) drugs. Treatment is prescribed and monitored by physicians who are specialists in the treatment of drug dependence. Treatment with BUPREN sublingual tablets is intended for use in adults and adolescents over 15 years of age.

How BUPREN works

BUPREN contain the active ingredients buprenorphine and naloxone. Buprenorphine acts as a substitute for opiate drugs like heroin or morphine and it helps withdrawal from opiate drugs over a period of time. When taken sublingually (under the tongue) as prescribed, naloxone has no effect, as it is very poorly absorbed. However, if BUPREN sublingual tablet is injected, naloxone will act to block the effects of other opiates like heroin or morphine, leading to bad withdrawal symptoms. Therefore, naloxone is included in BUPREN to discourage misuse by injection, (intravenous abuse) as it can cause very bad withdrawal symptoms. BUPREN sublingual tablet should be used exactly as prescribed.

Before you use BUPREN

When you must not take it

- If you are allergic (hypersensitive) to buprenorphine, naloxone or any of the other ingredients of BUPREN,
- If you have serious breathing problems,
- If you have serious problems with your liver,
- If you are intoxicated due to alcohol or have delirium tremens.

Using BUPREN, with food and drink

Do not take BUPREN together with alcoholic beverages as alcohol may possibly increase drowsiness induced by BUPREN.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. You should not use BUPREN, during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant. He will decide if your treatment should be continued with an alternative medication. Since this product will pass into your milk and may adversely affect the breast-fed child, you should discontinue breast-feeding while taking BUPREN.

Before you start to take it

Before taking BUPREN, tell your doctor if you have:

- If you are allergic (hypersensitive) to buprenorphine, naloxone or any of the other ingredients of BUPREN,
- If you have serious breathing problems,
- If you have serious problems with your liver,
- If you are intoxicated due to alcohol or have delirium tremens.

You may not be able to take BUPREN, or you may require a dosage adjustment or special monitoring during treatment if

you have any of the conditions listed above.

Taking other medicines

Taking Bupren with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine. Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness

Using other medicines may increase the undesirable effects of buprenorphine and use of these medicines must be carefully monitored:

- benzodiazepines
- tranquilizers
- anti-anxiety medicines
- anti-depressants
- some medicines used to treat blood pressure.

If your physician prescribes benzodiazepines, you must not take more than the prescribed dose. Taking this product with benzodiazepines (medicines used to treat anxiety or sleep disorders) may cause death due to respiratory failure.

The following medicines may increase the concentration of buprenorphine in the blood, so concomitant use of these medicines together with BUPREN should be closely monitored and could require in some cases a dose reduction by your doctor:

- anti-retrovirals (ritonavir, nelfinavir, indinavir)
- ketoconazole
- itraconazole

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

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How to use BUPREN

How much to use

Take BUPREN exactly as directed by your doctor. If you do not understand these directions, ask your pharmacist, nurse, or doctor to explain them to you.

The BUPREN tablets should be placed under the tongue and allowed to dissolve. This will take 5 to 10 minutes. If more than one tablet is prescribed per dose, your doctor may tell you to put all of the tablets under your tongue at the same time, or put 2 tablets under your tongue and allow them to dissolve completely, then put the next tablet or tablets under the tongue right away.

Do not chew or swallow the tablets. The medicine will not work this way and you may get withdrawal symptoms. Do not change the dose of BUPREN or take it more often than prescribed without first talking to your doctor. Do not inject ("shoot-up") BUPREN. Shooting-up is dangerous and may cause bad withdrawal symptoms.

When to take use

As advised by your doctor

How long to use it

The length of treatment will be determined individually by your doctor. After a time of successful treatment, the doctor may reduce the dose gradually to a lower maintenance dose. Depending on your condition, the BUPREN dose may continue to be reduced under careful medical supervision, until eventually it may be stopped.

Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

The effectiveness of this treatment depends:

- on the dose,
- in combination with the associated medical, psychological and social treatment.

If you have the impression that the effect of BUPREN is too strong or too weak, talk to your doctor or pharmacist.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take only the next regularly scheduled dose. Do not take a double dose of this medication.

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you take too much (overdosage)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using BUPREN

Things you must do

BUPREN can cause constipation. Drink plenty of water (six to eight full glasses a day) to lessen this side effect. Increasing the amount of fiber in your diet can also help to alleviate constipation.

Your doctor may want to perform blood tests or other forms of monitoring during treatment with BUPREN.

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking BUPREN

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Avoid alcohol while taking this medicine. Alcohol may dangerously increase drowsiness and dizziness caused by the medication.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give BUPREN to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Some people have died from respiratory failure (inability to breathe) because they misused buprenorphine or took it while in combination with other central nervous system depressants, such as alcohol, benzodiazepines (tranquilisers), or other opioids. Some cases of severe liver problems have occurred during treatment, although they may not necessarily have been caused by BUPREN. These injuries could be due to special conditions as viral infections (chronic C hepatitis), ongoing injection drug misuse, alcohol abuse, loss of appetite or when used together with other medications.

A number of medicines may alter the effects of BUPREN. These include: certain medicines for treating HIV/AIDS, certain medicines for treating fungal and bacterial infections, strong pain killers, cough medicines containing opioid-related substances, certain antidepressants including monoamine oxidase inhibitors, certain medicines used to treat fits or epilepsy (anti-convulsants), anti-anxiety medicines, sedatives, sedating antihistamines, certain medicines for antipsychotics, high blood pressure medicines.

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. This product can cause withdrawal symptoms if you take it less than six hours after you use a narcotic (e.g. morphine, heroin) or less than 24 hours after you use methadone. This product can cause sleepiness which may be increased by alcohol or anti-anxiety medicines. This product can cause dependence.

This product can be a target for people who abuse prescription medicine. Keep it in a safe place to protect it from theft. Do not give this medicine to anyone else. It can cause death or otherwise harm them. Advise your physician in case of:

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

This medicinal product may mask pain reflecting some diseases. Do not forget to advise your physician if you take this medicine. 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. This medicinal product in combination with medicines called monoamine oxidase inhibitors (MAOIs) may theoretically produce an exaggeration of the effects, based upon experience with morphine.

Advise your physician in case of:

- asthma or other breathing problems,
- kidney disease,
- liver disease.

- Serotonin syndrome: Bupren tablet may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

- Adrenal insufficiency: Long-term use of Bupren tablet may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms. Infertility: Long-term use of Bupren tablet may cause reduced fertility. It is

not known whether these effects on fertility are reversible.

Side effects

Possible Side Effects

Like all medicines, BUPREN can cause side effects, although not everybody gets them. You may need medical treatment if you get some of the side effects.

The side effects of BUPREN are listed as below:

- a) Difficulty in sleeping
- b) Constipation
- c) Nausea
- d) Sweating
- e) Headache
- f) Withdrawal syndrome

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers◇ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of BUPREN

Storage

Keep out of the reach and sight of children.

Storage below 30°C

Do not store any medicine in the bathroom, or near a sink, or on a window sill

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after "EXP" the expiry date refers to the last day of that month

Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

What it looks like

BUPREN 8MG/2MG: A white to off white hexagonal shaped tablet with a dimension of 11mmx10mm

BUPREN 2MG/0.5MG: A white to off white hexagonal shaped tablet with a dimension of 6.5mmx5.9mm

Ingredients

Active ingredient(s)

Buprenorphine hydrochloride
Naloxone hydrochloride

Inactive ingredients

Mannitol powder
Lactose monohydrate
Sodium citrate
Citric acid monohydrate
Corn starch
Corn starch (paste)
Sodium saccharin
Povidone
Lemon flavor
Colloidal Silicon Dioxide
Magnesium Stearate
Purified water

MAL no:

Bupren 2mg/0.5mg sublingual tablet (MAL15065041AZ)
Bupren 8mg/2mg sublingual tablet5mg (MAL15065042AZ)

Manufacturer

Noripharma Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Mile off Jalan Meru,
41050 Klang, Selangor.

Product Registration Holder:

Pahang Pharmacy Sdn. Bhd.
Lot 5030, Jalan Teratai,
5 ½ Mile off Jalan Meru,
41050 Klang, Selangor.

Date of Revision:

February 2022

Serial number:

NPRA(R2/1)210908/746