

BUPRENORPHINE NALOXONE BNM Sublingual Tablets

Buprenorphine Hydrochloride - Naloxone Hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given BUPRENORPHINE NALOXONE BNM. This leaflet answers some common questions about BUPRENORPHINE NALOXONE BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz. Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BUPRENORPHINE NALOXONE BNM against the benefits you may gain and he/she believes it will help in your treatment.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What BUPRENORPHINE NALOXONE BNM is used for

BUPRENORPHINE NALOXONE BNM is used as part of a medical, social and psychological treatment program for patients' dependent on opioids like heroin, morphine, oxycodone or codeine.

BUPRENORPHINE NALOXONE BNM is used to help such patients to regain control over their lives.

BUPRENORPHINE NALOXONE BNM tablets contain the active ingredients buprenorphine hydrochloride and naloxone hydrochloride. Buprenorphine acts as a substitute for opioids like heroin and it helps withdrawal from opioids 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 BUPRENORPHINE NALOXONE BNM is injected, naloxone will act to block the effects of other opioids like heroin, methadone or morphine, leading to bad withdrawal symptoms. Therefore, naloxone is included in BUPRENORPHINE NALOXONE BNM to discourage misuse by injection, as it can cause very bad withdrawal symptoms.

BUPRENORPHINE NALOXONE BNM should be used exactly as prescribed by your doctor.

Ask your doctor if you have any questions about why BUPRENORPHINE NALOXONE BNM has been prescribed for you.

BUPRENORPHINE NALOXONE BNM is only available with a doctor's prescription.

Before you take BUPRENORPHINE NALOXONE BNM

BUPRENORPHINE NALOXONE BNM is not suitable for everyone

When you must not take it

Do not take BUPRENORPHINE NALOXONE BNM:

- If you are under the age of 16 years.
- If you are allergic to buprenorphine or to naloxone or to any of the other ingredients in this medicine (see Product Description below).
- If you have serious breathing problems.
- If you have serious problems with your liver, or if your doctor detects the development of such a problem during treatment.
- If you are intoxicated due to CNS depressant medicines (e.g. tranquillisers, sedative/hypnotics, narcotic analgesics, anti-anxiety medicines, antipsychotics), alcohol or have delirium tremens (the 'shakes' and hallucinations).
- Do not take BUPRENORPHINE NALOXONE BNM if the package is torn, shows signs of tampering or the tablets do not look quite right.

Do not take BUPRENORPHINE NALOXONE BNM after the expiry date printed on the pack.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take BUPRENORPHINE NALOXONE BNM

Tell your doctor if you have any of the following before treatment, or develop them during treatment, as your doctor may need to adjust your dose of BUPRENORPHINE NALOXONE BNM.

- if you are pregnant
- if you are breastfeeding
- asthma or other breathing problems
- thyroid problems
- prostate problems
- problems with excess alcohol use
- problems with drowsiness
- Adrenal gland problems (e.g. Addison's disease)
- Kyphoscoliosis (hunchback disease)
- low blood pressure
- urination problems
- kidney problems
- liver problems
- if you have head injuries or in a condition where you have increased pressure within your head
- if you have problems related to the biliary tract
- stomach (abdominal pains)
- if you have severe mental problems or hallucinations (seeing or hearing things that are not really there)
- if you have a history of seizures

Some people have died from respiratory failure (inability to breathe) when using benzodiazepines

(medicines used to treat anxiety or sleeping problems) at the same time as buprenorphine naloxone tablets. **While you are being treated with BUPRENORPHINE NALOXONE BNM, do not use benzodiazepines unless they have been prescribed by your doctor.**

BUPRENORPHINE NALOXONE BNM may cause fatal respiratory failure if children accidentally ingest it. **Keep this medicine out of reach and sight of children.**

As BUPRENORPHINE NALOXONE BNM contains naloxone, it is highly likely to produce strong opioid withdrawal symptoms if misused as an injection while you are still experiencing the effects of other opioids.

When taken sublingually BUPRENORPHINE NALOXONE BNM can cause withdrawal symptoms if you take it less than six hours after you use a short acting opioid (such as morphine or heroin) or less than 24 hours after a long acting opioid (such as methadone).

BUPRENORPHINE NALOXONE BNM can cause drug dependence. This means that you can get withdrawal symptoms if you stop using the medicine too quickly. Withdrawal symptoms may be delayed in some cases.

BUPRENORPHINE NALOXONE BNM is not intended for occasional use and should be taken only as prescribed.

BUPRENORPHINE NALOXONE BNM may cause drowsiness, which may be made worse if you also drink alcohol or take sedatives or anti-anxiety medicines. If you are drowsy, do not drive or operate machinery.

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

Athletes should be aware that this medicine may cause a positive reaction to "anti-doping" tests.

The safety and effectiveness in patients over 65 years of age have not been established.

Your doctor may ask you to have additional blood tests to see if this medication is right for you.

If you have not told your doctor about any of the above, tell him/her before you start taking BUPRENORPHINE NALOXONE BNM.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop, before you begin treatment with BUPRENORPHINE NALOXONE BNM.

Some medicines and BUPRENORPHINE NALOXONE BNM may interfere with each other. These include:

- certain medicines for treating HIV/AIDS medicines
- 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)
- sedating antihistamines
- sedatives
- anti-anxiety medicines
- certain medicines for high blood pressure
- medicines used to treat alcohol dependence
- antipsychotic medicines
- naltrexone.

Tell your doctor if you are scheduled to have surgery using a general anaesthetic.

Do not drink alcohol or take medicines that contain alcohol while you are being treated with BUPRENORPHINE NALOXONE BNM.

Alcohol and certain other medicines (as listed above) may increase the sedative effects of buprenorphine, which can make driving and operating machinery hazardous.

Some people have died when using sedatives (benzodiazepines) or other depressants or alcohol or other opioids at the same time as BUPRENORPHINE NALOXONE BNM. You should not use benzodiazepines (medicines used to treat anxiety or sleeping problems) whilst you are taking BUPRENORPHINE NALOXONE BNM unless they are prescribed by your doctor.

How to take BUPRENORPHINE NALOXONE BNM

Do not take BUPRENORPHINE NALOXONE BNM to treat any condition other than the one prescribed for by your doctor.

Do not give BUPRENORPHINE NALOXONE BNM to anyone else, even if their symptoms seem the same as yours. It may harm them.

The tablets are taken sublingually. This means that you place the tablet under your tongue and allow it to dissolve, which may take 2 to 10 minutes. This is the only way the tablets should be taken. Do not swallow or consume food or drink until the tablet is completely dissolved. You may take the tablets all at once or in two lots, the second after the first lot has dissolved. Do not split or break the tablets.

The tablets will not work if you chew or swallow them whole.

Do not inject BUPRENORPHINE NALOXONE BNM; patients have died from injecting buprenorphine and naloxone. Additionally, when injecting buprenorphine and naloxone and also taking benzodiazepines (medicines used to treat anxiety or sleeping problems), people were even more likely to die.

How much to take

BUPRENORPHINE NALOXONE BNM is only for adults and children over the age of 16 years. Your doctor will tell you how much BUPRENORPHINE NALOXONE BNM to take and you should always follow medical advice.

Each BUPRENORPHINE NALOXONE BNM sublingual tablet contains buprenorphine and naloxone. BUPRENORPHINE NALOXONE BNM containing 2mg buprenorphine and 0.5mg naloxone is referred to as the '2mg' tablets and BUPRENORPHINE NALOXONE BNM containing 8mg buprenorphine and 2mg naloxone is referred to as the '8mg' tablets.

On the first day, the usual starting dose is 4-8 mg BUPRENORPHINE-NALOXONE BNM with an additional 4 mg depending on your needs, as determined by your treating doctor.

- For patients who are still using short acting opioids such as heroin, morphine, oxycodone or codeine: when starting treatment, the dose of BUPRENORPHINE-NALOXONE BNM should be taken when the first signs of craving appear or at least 6 hours after your last use of opioid or when the first signs of craving appear.
- For patients receiving methadone: before beginning treatment with BUPRENORPHINE NALOXONE BNM, your doctor will probably reduce your dose of methadone to the minimum methadone daily dose that you can tolerate. The first dose of

BUPRENORPHINE NALOXONE BNM should preferably be taken when the first signs of craving appear and at least 24 hours after your last dose of methadone.

BUPRENORPHINE NALOXONE BNM may cause withdrawal symptoms if taken too soon after methadone or an illicit opioid.

During your treatment, your doctor may increase your dose of BUPRENORPHINE NALOXONE BNM to a maximum daily dose of 32mg, depending upon your response to treatment.

After a period of successful treatment, 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 tablets, as this may cause withdrawal symptoms.

If you forget to take it

If you forget to take a dose of BUPRENORPHINE NALOXONE BNM, take it as soon as you remember. If you are unsure consult your doctor.

In an emergency

Have family members or friends tell hospital or ambulance staff that you are dependent on opioids (narcotics) and are being treated with BUPRENORPHINE NALOXONE BNM.

If you take too much (overdose)

If you think that you or anyone else may have taken too much BUPRENORPHINE NALOXONE BNM, immediately telephone your doctor or National Poison Centre telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you take too much BUPRENORPHINE NALOXONE BNM, some of the symptoms which may or may not occur are listed in the side effects section of this leaflet.

Side effects

Like all medicines, BUPRENORPHINE NALOXONE BNM may have unwanted side effects which may need medical treatment.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Very common side effects reported with the use of BUPRENORPHINE NALOXONE BNM were:

- difficulty sleeping,
- headache,
- constipation,
- nausea,
- sweating.

Many of the common side effects reported with the use of BUPRENORPHINE NALOXONE BNM were related to opioid withdrawal symptoms, such as:

- anxiety, nervousness, depression, loss of appetite, abnormal thinking, loss of libido, drowsiness, dizziness
- malaise, fatigue,
- pain in the abdomen, back, joints and muscles, leg cramps, muscle weakness,
- flu like symptoms, such as chills, fever, sore throat, coughing, runny nose, watery eyes, sore throat and sweating,

- upset stomach and diarrhoea, pins and needles,
- vomiting, diarrhea, wind, indigestion,
- rash and itching,
- difficulty urinating, impotence,
- chest pain.

Other side effects which have occurred are:

- migraine,
- abnormal vision,
- tremor,
- reduced sex drive,
- chest, back, stomach, muscle, joint pain,
- vomiting, decreased weight,
- hives,
- flushing, swelling of the legs and arms,
- cough, respiratory infection,
- urinary track infection, vaginal infection,
- anaemia,
- eye infection,
- palpitation,
- asthma,
- blood in vomit,
- jaundice,
- swollen joints,
- thoughts of suicide.

If you think you are experiencing any of the above side effects, or any other side effects, you should tell your doctor immediately.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

- There have been rare cases of life-threatening severe hypersensitivity reactions with symptoms of severe difficulty in breathing, swelling, of the face, lips, mouth or throat.

- Some serious cases of severe liver problems have occurred during treatment. If you develop severe fatigue, have no appetite or if your skin or eyes look yellow, you have light coloured bowel motions or dark coloured urine, tell your doctor immediately

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

After using BUPRENORPHINE NALOXONE BNM

If you stop taking BUPRENORPHINE NALOXONE BNM and start taking heroin again, you are at risk of being more sensitive to opioids, which could be dangerous. You should talk to your doctor if you start taking heroin again.

Storage

BUPRENORPHINE NALOXONE BNM is packed in Alu-Alu blisters.

BUPRENORPHINE NALOXONE BNM contains a narcotic that can be a target for people who abuse prescription medicines or street drugs. Therefore, keep your tablets in a safe place to protect them from theft. Keep out of reach and sight of children. Never give them to anyone else.

The tablets should be stored below 30°C in the original package. BUPRENORPHINE NALOXONE BNM should be protected from moisture and prolonged exposure to light. As with all medicines, keep out of the reach of children.

Do not use BUPRENORPHINE NALOXONE BNM after the expiry date that is stamped on the pack.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your

pharmacist what to do with any medicine that is left over.

Sponsor details

Product description

What BUPRENORPHINE NALOXONE BNM looks like

BUPRENORPHINE NALOXONE BNM is available in blister packs of 28 tablets.

BUPRENORPHINE NALOXONE BNM 2mg/0.5mg are white to off-white, round and biconvex tablets, with embossing "L" on one side and a diameter of about 6.5 mm.

BUPRENORPHINE NALOXONE BNM 8mg/2mg are white to off-white, round and biconvex tablets, with embossing "H" on one side and a diameter of about 11.5 mm.

Ingredients

Each BUPRENORPHINE NALOXONE BNM 2mg/0.5mg sublingual tablet contains 2mg buprenorphine (as hydrochloride) and 0.5mg naloxone (as hydrochloride dihydrate) as active ingredients.

Each BUPRENORPHINE NALOXONE BNM 8mg/2mg sublingual tablet contains 8mg buprenorphine (as hydrochloride) and 2mg naloxone (as hydrochloride dihydrate) as active ingredients.

BUPRENORPHINE NALOXONE BNM tablets also contain the following inactive ingredients:

- Lactose monohydrate
- mannitol
- maize starch
- povidone
- citric acid monohydrate
- sodium citrate
- magnesium stearate
- acesulfame potassium
- a lemon flavour
- lime flavour

BNM Group
39 Anzac Road
Browns Bay
Auckland 0753

Phone 0800 565 633

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