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PACKAGE LEAFLET: INFORMATION FOR THE USER

Addnok 0.4, 2 and 8 mg sublingual tablets

buprenorphine

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 ADDNOK IS AND WHAT IT IS USED FOR

Addnok is used:
- if you are addicted to opioids, e. g. heroin or morphine, within a framework of medical, social and psychological treatment.

The treatment is prescribed and monitored by doctors specialized in treating drug addiction.

2. BEFORE YOU TAKE ADDNOK

Do not take Addnok if you:
- are allergic (hypersensitive) to buprenorphine or any of the other ingredients of Addnok
- suffer from serious breathing difficulties
- suffer from a seriously reduced liver function
- suffer from alcoholism or delirium tremens.

Take special care with Addnok if you:
- have taken morphine or heroin (opioids) less than 6 hours ago, as withdrawal symptoms can occur
- have taken methadone less than 24 hours ago, as withdrawal symptoms can occur (if you use methadone your dose may have to be adjusted before you take buprenorphine, see section 3)
- suffer from asthma or breathing difficulties
- suffer from reduced function of the kidneys or the liver. If you suffer from serious liver insufficiency you must not take buprenorphine
- suffer from low bloodpressure
- have difficulty passing urine (because of an enlarged prostate gland or urethral stricture)
- suffer from a head injury and have an increased intracranial pressure.

Observe that Addnok may:
- cause dependence
- cause a positive reaction to "anti doping tests"
- cause your blood pressure to drop suddenly, causing you to feel dizzy and unwell if you get up too quickly from sitting or lying down
- mask other diseases where pain is a symptom since buprenorphine has a pain relieving effect.

Taking other medicines

Buprenorphine may influence the efffect of other medicines and other medicines may influence the effect of buprenorphine.

It is therefore important you tell your doctor if you use any of the following medicines:
- medicine used in the treatment of anxiety and disquiet and sleeping difficulties (benzodiazepines and anxiolytics other than benzodiazepines)
- medicine used in the treatment of skin infection in the scalp (ketoconazole, itraconazole)
- medicine used in the treatment of certain infections (rifampicin)
- medicine used in the treatment of HIV (ritonavir, indinavir, nelfinavir)
- some types of medicine used in the treatment of allergy
- some types of medicine used in the treatment of depression
- medicine used in the treatment of migraine, hot flushes and abstinences as a result of medicine abuse (clonidine)
- cough medicine (dextromethorphan, noscapine)
- painkillers (morphine and morphine-like substances)
- medicine containing alcohol
- medicine used in the treatment of epilepsy (phenobarbital, phenytoin, carbamazepine)
- medicine used in the treatment of psychosis (neuroleptics)
- medicine used as sedatives and to relieve convulsions (barbiturates).

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

Taking Addnok with food and drink

You can take Addnok independently of a meal.

Alcohol

Do not drink alcohol when you are treated with Addnok since alcohol will increase the sedative effect of buprenorphine.

Pregnancy and breast-feeding

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

Pregnancy

You should not use buprenorphine during your pregnancy. But if your doctor finds it appropriate an exception can be made for the first 3 months of your pregnancy.

Breast-feeding

Do not take buprenorphine if you are breast-feeding.

Driving and using machines

Addnok can be sedating, cause fainting and dizziness, and therefore it can reduce the ability to drive and use machines.

Do not drive or use machines if you feel dizzy or drowsy. This usually occurs at the beginning of treatment and when the dose is increased.

Important information about some of the ingredients of Addnok

Addnok contains 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

3. HOW TO TAKE ADDNOK

Always take Addnok exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This is the way you take Addnok

A sublingual tablet is a tablet that is taken under your tongue. Keep the tablet dose under your tongue until it dissolves - normally it takes 5-10 minutes. Do not swallow, crush or chew the tablet.

Usual dose if you are/have:

Adults or elderly:

Your initial dose will be between 0.8 to 4 mg (one tablet once daily). Your doctor will increase your dose according to your response to the treatment until you have a stable dose, 16 mg daily is often sufficient. The maximum daily dose is 24 mg. Your doctor will then individually determine the length of your treatment and gradually reduce your dose. Do not change the treatment in any way or stop treatment without the agreement of the doctor who is treating you.

Children and adolescents (younger than 18 years):

Children and adolescents under the age of 18 must not use Addnok.

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Reduced kidney or liver function:
If you have problems with your kidneys or liver your dose may have to be reduced. Talk to your doctor. If you suffer from serious liver insufficiency you must not take buprenorphine.

Concomitant methadone treatment
Your dose of methadone has to be reduced to a maximum of 30 mg daily before starting treatment with Addnok. Contact your doctor if you experience withdrawal symptoms (sweating, disquiet or restlessness).

If you take more Addnok than you should
In case of overdose of buprenorphine, you must go or be taken immediately to an emergency centre or hospital for treatment.

Symptoms of an overdose is breathing difficulties, slowly breathing or heart symptoms.

Toxic poisoning has been observed after misuse (overdose or wrong administration) and in worst case it can result in stop of breathing/heart failure and/or liver damage.

If you forget to take Addnok
Do not take a double dose to make up for a forgotten dose.

If you stop taking Addnok
Do not stop the treatment yourself, but ask your doctor how to end the treatment. A sudden interruption can cause withdrawal symptoms (sweating, disquiet and restlessness).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

You should stop taking Addnok and see your doctor immediately if you experience symptoms of angioneurotic oedema, such as:
- swollen face, tongue or pharynx
- difficulty to swallow
- hives and difficulties to breath

Addiction to Addnok
Please observe that Addnok may cause dependence.

Common side effects (occuring in more than 1 but less than 10 in 100 patients):
Headache, fainting, dizziness, obstipation, nausea, vomiting, insomnia, drowsiness, feeling of weakness, drop in blood pressure on changing position from sitting or lying down to standing, sweating.

In long term use of buprenorphine, the common undesirable effects diminish successively. However constipation and sweating often remain.

Rare side effects (occurring in more than 1 but less than 10 in 10,000 patients):
Hallucinations, respiratory depression, bronchial spasm, damage of the liver, hepatitis, anafylatic shock, angioneurotic oedema, urine retention.

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 ADDNOK

Keep out of the reach and sight of children.

Do not use Addnok after the expiry date which is stated on the carton and on the blister after Exp. The expiry date refers to the last day of that month.

Does not require any special storage conditions.

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.

6. FURTHER INFORMATION

What Addnok contains
The active substance is buprenorphine as buprenorphine hydrochloride. Each sublingual tablet contains 0.4 mg, 2 mg and 8 mg buprenorphine respectively.

The other ingredients are lactose monohydrate, mannitol (E421), maize starch, citric acid (E330), sodium citrate (E331), povidone (E1201), magnesium stearate (E470b).

The 0.4 mg sublingual tablets also contain: Talc (E553b) and colloidal anhydrous silica.

What Addnok looks like and contents of the pack
Addnok 0.4 mg is a round, biconvex and white sublingual tablet.

Addnok 2 mg is an oval, biconvex and white sublingual tablet with "2" embossed on one side.

Addnok 8 mg is an oval, biconvex and white sublingual tablet with "8" embossed on one side.

Addnok is packed in blister packs of 7, 14 and 28 sublingual tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Activase Pharmaceuticals Ltd., 11 Boumpoulinas St.,
1060 Nicosia, Cyprus

Manufacturer
Basic Pharma Manufacturing B.V., Burgemeester Lemmensstraat 352, 6163 JT Geleen, The Netherlands

DDSA Pharmaceuticals Ltd, 310 Old Brompton Road,
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Laboratorios Atral, S.A.
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Vala do Carregado, Castanheira do Ribatejo, 2600-726, Portugal
The manufacturer (Laboratorios Atral, S.A.) is only valid for the 2 mg & 8 mg Addnok Sublingual Tablets.

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Strada Statale 67, Fraz. Granatieri, 50018 Scandicci (Firenze), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden:	Subuphine
Ireland:	Buprenorphine 0.4 mg Sublingual Tablets
	Buprenorphine 2 mg Sublingual Tablets
	Buprenorphine 8 mg Sublingual Tablets
United Kingdom:	Addnok 0.4 mg Sublingual Tablets
	Addnok 2 mg Sublingual Tablets
	Addnok 8 mg Sublingual Tablets
Germany:	Buprenorphine 0.4 mg Sublingualtabletten
	Buprenorphine 2 mg Sublingualtabletten
	Buprenorphine 8 mg Sublingualtabletten
Czech Republic:	Addnok 0.4 mg Sublingual Tablets
	Addnok 2 mg Sublingual Tablets
	Addnok 8 mg Sublingual Tablets
Slovenia:	Addnok 0.4 mg podjezične tablete
	Addnok 2 mg podjezične tablete
	Addnok 8 mg podjezične tablete

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