PIL0580.1
PACKAGE LEAFLET: INFORMATION FOR THE USER

Espranor® 8mg oral lyophilisate

(buprenorphine hydrochloride)

The name of your medicine is Espranor® 8mg oral lyophilisate but it will be referred as Espranor throughout this leaflet. Other lower strength of this medicine is also available.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet:

1. What Espranor is and what it is used for

Espranor oral lyophilisate is a freeze-dried wafer which dissolves rapidly on the tongue.

Espranor is used in adults and adolescent over 15 years of age, as part of a medical, social and psychological treatment programme for addiction.

Espranor contains buprenorphine, an opioid (narcotic) analgesic. When it is used for the treatment of patients addicted to opiate (narcotic) drugs, such as morphine or heroin, it acts as a substitute for these drugs and therefore aids the patient in withdrawing from them over a period of time.

If treatment is stopped abruptly, withdrawal symptoms can occur.

2. What you need to know before you take Espranor

Espranor is not interchangeable with other oral buprenorphine products and the dose of Espranor may differ from the dose of other buprenorphine products

Do not take Espranor if:
- You are allergic (hypersensitive) to buprenorphine or any of the other ingredients in Espranor (see section 6)
- You have severe breathing problems
- You have severe liver problems
- You are alcohol dependent or suffer from acute alcoholism including 'the shakes' or hallucinations
- You are pregnant (unless your doctor tells you to take it)

Warnings and Precautions
Talk to your doctor, pharmacist or nurse before taking Espranor:
- If you suffer breathing problems e.g. asthma
- If you have liver problems
- If you have kidney problems
- If you have low blood pressure
- If you have recently suffered a head injury or brain disease
- If you have a urinary disorder (especially linked to enlarged prostrate in men)
- If you have thyroid problems
- If you have adrenocortical disorder (e.g. Addison's disease)
- If you are breastfeeding a baby
- If you have depression or other conditions that are treated with antidepressants.

The use of these medicines together with Espranor can lead to serotonin syndrome, a potentially lifethreatening condition (see "Other medicines and Espranor").

If any of the above applies to you, please tell your doctor before taking Espranor as your doctor may need to reduce your dose of Espranor or you may need additional treatment to control it.

Important things to be aware of:
Additional monitoring
You may be more closely monitored by your doctor if you are below the age of 18. **Espranor should not be given to children or adolescents under 15 years old.**

Misuse and abuse
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. Do not give this medicine to anyone else. It can cause death or otherwise harm them.

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.
This medicine may cause severe, possibly fatal, respiratory depression (reduced ability to breathe) in children and non-dependent people who accidentally or deliberately take it.

Dependence
This product can cause dependence.

Withdrawal symptoms
This product can cause withdrawal symptoms if you take it less than six 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.

This medicine can also cause withdrawal symptoms if you stop taking it abruptly.

Liver damage
Liver damage has been reported after taking this medicine, 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 Espranor.

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 Espranor
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 Espranor and may sometimes cause very serious reactions. Do not take any other medicines whilst taking Espranor without first talking to your doctor, especially:
- Anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Espranor 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.

The following medicines have sedative effects (make you feel sleepy/drowsy). These effects are increased if these medicines are taken while you are being treated with Espranor:
- Benzodiazepines (medicines used to treat anxiety or sleep disorders) e.g. diazepam (valium). Your doctor will prescribe the correct dose for you. Taking the wrong dose of benzodiazepines may cause death due to respiratory failure (inability to breathe).
- Barbiturates e.g. phenobarbital
- Other opioids or opioid derivatives e.g. morphine, strong pain killers or cough medicines
- Certain antidepressants e.g. fluoxetine (Prozac)
- Monoamine oxidase inhibitors (MAOI) (medicines used to treat severe depression) e.g. phenelzine
- Medicines that cause drowsiness such as antihistamines or sedatives
- Certain drugs used to treat high blood pressure
- Antipsychotic drugs (medicines used to treat certain mental disorders)

If you are taking any of the following medicines, your doctor may need to prescribe a lower dose of Espranor:
- Ketoconazole (medicine used to treat a fungal infection which can increase the levels of Espranor in your blood if both are taken at the same time)
- Gestodene (found in some contraceptive pills)
- Drugs used to treat HIV e.g. ritonavir, indinavir and saquinavir
- Phenprocoumon (a blood thinning medicine)

If you are taking any of the following medicines, your doctor may need to prescribe a higher dose of Espranor:
- Enzyme inducers e.g. phenobarbital, carbamazepine, phenytoin and rifampicin

Naltrexone may prevent the therapeutic effects of Espranor.
If currently taking this medicine followed by concomitant use of naltrexone, you may experience a sudden onset of prolonged and intense withdrawal.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Espranor with food, drink and alcohol
Espranor should not be taken at the same time as food or drink.
You should not drink alcohol or take any medicines that contain alcohol while taking Espranor as this will increase the risk of drowsiness, respiratory depression and fatal overdose.

Pregnancy, breast-feeding and fertility
Before taking Espranor, tell your doctor if you are pregnant or trying to become pregnant. If you become pregnant during treatment with Espranor, tell your doctor straight away.
Since Espranor is passed into breast milk, you should not breast feed while taking this medicine.
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 tranquilizers or antianxiety drugs. If you are drowsy, do not drive or operate machinery.

This medicine can affect your ability to drive.
Do not drive whilst taking this medicine until you know how this medicine affects you.
It may be an offence to drive if your ability to drive safely is affected.
There is further information for patients who are intending to drive in Great Britain – go to https://www.gov.uk/drugdriving-law.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine

Espranor contains aspartame
This medicine contains 2.0 mg aspartame in each 8 mg oral lyophilisate

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Espranor

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

When to start taking Espranor
Starting Espranor treatment if you are dependent on heroin or a short acting opioid – your first dose of Espranor should be taken at least 6 hours after you last used the opioid or when signs of withdrawal appear.

Starting Espranor treatment if you are dependent on methadone or a long acting opioid – you will not start treatment with this medicine until your daily dose of methadone is 30 mg a day or less. The first dose of Espranor should be taken when signs of withdrawal appear, but not less than 24 hours after you last used methadone.

For the first 24 hours of treatment, you may feel uncomfortable with some mild opiate withdrawal symptoms e.g. sweating, feeling sick (see section 4 Possible side effects).

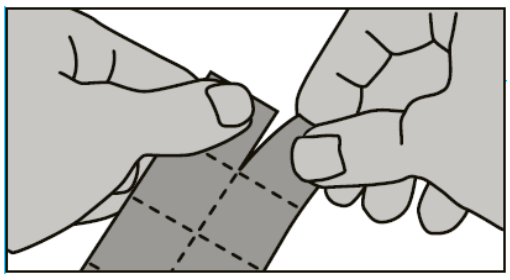
How much to take
Your doctor will decide what dose you need to start treatment with.
During treatment your doctor will adjust your dose depending upon your response. The maximum dose is 18 mg daily. After a period of successful treatment, your doctor may gradually reduce your dose and depending on your condition, may stop it altogether.

Do not suddenly stop taking Espranor as this may lead to withdrawal symptoms.

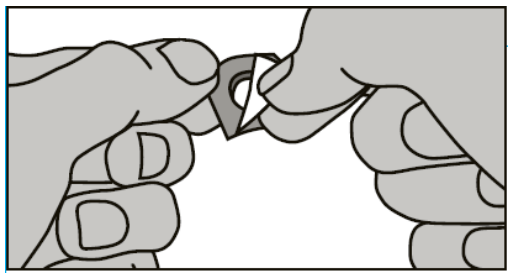
Instructions for use

Take Espranor **by placing ON your tongue,** not under your tongue.

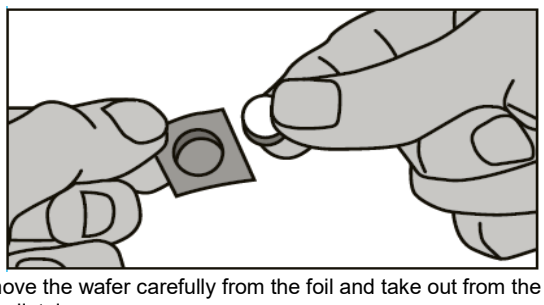
Espranor is sensitive to moisture. Make sure your hands are dry before handling the wafer. Take the wafer by following the instructions below:



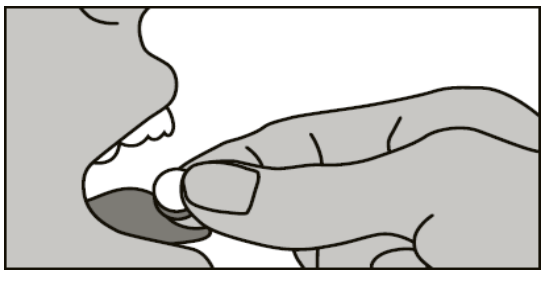
1. Tear a square off the blister pack along the perforated lines.



2. The foil is easily peelable. Do not force the wafer through the foil as it is fragile and can easily break. Instead, fold back the foil and then peel it off.



3. Remove the wafer carefully from the foil and take out from the packaging immediately.



4. Place the wafer on the tongue and close your mouth. Allow it to remain there for a few seconds until it has dissolved. Try to avoid swallowing during the first 2 minutes.

Do not eat or drink for at least 5 minutes.

If you take more Espranor than you should
Tell your doctor immediately or contact your nearest hospital casualty department. Remember to take the pack and any remaining wafers with you.

If you forget to take Espranor
You should tell your doctor and follow their instructions.
Do not take a double dose to make up for the missed dose, unless your doctor tells you to.

If you stop taking Espranor
Do not suddenly stop taking the wafers unless told to do so by your doctor, as this may cause withdrawal symptoms.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

For the first 24 hours of treatment, you may feel uncomfortable with some mild opiate withdrawal symptoms.

Tell your doctor immediately or seek urgent medical attention if you experience uncommon side effects, such as:
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, severe hives/nettle rash. These may be signs of a life-threatening allergic reaction.
- feeling sleepy and uncoordinated, have blurred vision, have slurred speech, cannot think well or clearly, or your breathing gets much slower than is normal for you.

Also tell your doctor immediately if you experience uncommon side effects such as:
- severe tiredness, itching with yellowing of skin or eyes. These may be symptoms of liver damage.
- seeing of hearing things that are not there (hallucination)

Very common side effects (may affect more than 1 in 10 people) include:
Insomnia (inability to sleep), constipation, feeling or being sick (nausea), sweating, headache, drug withdrawal syndrome.

Common side effects (may affect up to 1 in 10 people) are:
Weight loss, swelling (hands and feet), tiredness, drowsiness, anxiety, nervousness, tingling, depression, decreased sexual drive, increase in muscle tension, abnormal thinking, increased tearing (watering eyes) or other tearing disorder, blurred vision, flushing, increased blood pressure, palpitations, widening of blood vessel, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach or other stomach discomfort, diarrhoea, abnormal liver function, flatulence, vomiting, numbness of the tongue or mouth, rash, itching, hives, pain, joint pain, muscle pain, leg cramps (muscle spasm), difficulty in getting or keeping an erection, urine abnormality, abdominal pain, back pain, weakness, infection, chills, chest pain, fever, flu-like symptoms,
feeling of general discomfort, accidental injury caused by loss of alertness or co-ordination, faintness and dizziness, drop in blood pressure on changing position from sitting or lying down to standing.

Uncommon side effects (may affect up to 1 in 100 people) are:
Swollen glands, agitation, tremor, abnormal dream, excessive muscle activity. Not feeling like yourself , medicine dependence, amnesia (memory disturbance), loss of interest, exaggerated feeling of well-being, convulsion (fits), speech disorder, small pupil size, difficulty urinating, eye inflammation or infection, rapid or slow heart beat, low blood pressure, myocardial infarction (heart attack), chest tightness, Shortness of breath, asthma, yawning, pain and sores in mouth, tongue discolouration, acne, skin nodule, hair loss, dry or scaling skin, inflammation of joints, urinary tract infection, abnormal blood tests, loss of appetite, blood in urine, abnormal ejaculation, menstrual or vaginal problems, kidney stone, sensitivity to heat or cold, heat stroke, feelings of hostility.

Rare side effects (may affect up to 1 in 1000 people) are:
Slow or difficult breathing, liver injury with or without jaundice, swelling of face and throat or life threatening allergic reactions.

Side effects with unknown frequency (frequency cannot be estimated from the available data) include:
Sudden withdrawal syndrome caused by taking Espranor too soon after use of illicit opioids, drug withdrawal syndrome in newborn.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you are not sure what the side effects listed are, ask your doctor to explain them to you.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: 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 Espranor

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 blister after EXP. The expiry date refers to the last day of that month.

Store in the original package (blister) to protect from light and moisture. This medicinal product does not require any special temperature storage conditions.

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.

If your medicine shows any signs of deterioration, you should seek the advice of your pharmacist.

6. Contents of the pack and other information

What Espranor contains:
- The active substance is buprenorphine.
- Each oral lyophilisate contains 8mg of buprenorphine (as hydrochloride).
- The other ingredients are gelatin, mannitol, aspartame, mint flavour and citric acid.

What Espranor looks like and the contents of the pack
Espranor 8 mg oral lyophilisate is a white to off-white circular oral lyophilisate (wafer) marked with “M8” on one side.

Your medicine is available in blisters containing 7 x 1 oral lyophilisates or 28 x 1 oral lyophilisates in an outer carton.

Procured from within the EU and repackaged by PL holder:
PilsCo Ltd., 10-16 Colvilles Place, East Kilbride, G75 0SN.

Manufactured by:
Macarthys Laboratories (T/A Martindale Pharmaceuticals)
Bampton Road, Harold Hill, Romford, Essex, RM3 8UG,
United Kingdom.
Or
Ethypharm, Chemin de la Poudriere, 76120 Le Grand Quevilly, France.

PL 39467/0580 POM CD

Espranor® 8mg oral lyophilisate

Blind or partially sighted? Is this leaflet hard to see or read? Call 0800 198 5000 to obtain the leaflet on a format suitable for you.

Leaflet revision date: 23/12/2021