

DESUD PLUS 8 MG/2 MG SUBLINGUAL TABLETS

Buprenorphine 8mg / Naloxone 2mg

What is in this leaflet

This leaflet answers some common questions about Desud Plus.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Desud Plus against the benefits expected for you.

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 you have any concerns about taking this medicine, talk to your doctor or pharmacist.

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.

Keep this leaflet with your medicine.

You may need to read it again.

What Desud Plus is used for

Desud Plus 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 Desud Plus is intended for use in adults and adolescents over 15 years of

age. Desud Plus should be used only with caution in adolescents aged $15 \leq 18$.

How Desud Plus works

Desud Plus works by targeting receptors and deterring intravenous misuse of this product, thus suppressing withdrawal symptoms and reducing cravings.

If taken properly, Desud Plus will not make you high, instead it will reduce withdrawal symptoms and eventually lead to the remission of opiate addiction.

Before you use Desud Plus

When you must not take it

Do not take Desud Plus if you have:

- Hypersensitivity towards Buprenorphine, Naloxone, or any component of this product
- Severe respiratory insufficiency
- Severe hepatic insufficiency
- Acute alcoholism or delirium tremens
- Are pregnant and/or breastfeeding

Before you start to take it

Do not take Desud Plus together with alcoholic drinks or medications containing alcohol. Alcohol increases the sedative effect of buprenorphine, which can make driving vehicles and operating machinery hazardous.

Advise your physician in case of:

- Recent head injury or brain

disease

- Decrease of blood pressure
- In men: urinary disorders (especially linked to enlarged prostate)
- Asthma or breathing problems
- Kidney disease
- Liver disease

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

Taking other medicines

This product should be used cautiously together with:

- Benzodiazepines
- Other central nervous system depressants; other opioid derivatives (analgesics and antitussives); certain antidepressants, sedative H1-receptor antagonists, barbiturates, benzodiazepines, anxiolytics other than benzodiazepines, neuroleptics, clonidine and related substances
- Anti-retrovirals, ketoconazole, itraconazole, and other CYP3A4 Inhibitors
- Phenobarbital, carbamazepine, phenytoin, rifampicin and other CYP3A4 Inducers

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.

How to take Desud Plus

How much to take

Your doctor will prescribe the most suitable dose for you. During the duration of treatment, your doctor may adjust the dose, depending on your response.

To maximise the benefits of Desud Plus, you must inform your doctor about all the medicines you are taking, including alcohol, medicines containing alcohol, street drugs, and any prescription medicine you are taking that had not been prescribed to you by your doctor.

When to take it

Take the tablets strictly based on your prescription schedule by your doctor.

How long to take it

The treatment duration will be determined by your doctor.

After a period of successful treatment, your doctor may reduce the dose gradually to a lower maintenance dose. Depending on your condition, the Desud Plus 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, social and psychological treatment.

If you have the impression that the effect of Desud Plus is too strong or too weak, talk to your

doctor or pharmacist.

If you forget to take it

Contact your doctor or pharmacist immediately and ask for further advice.

If you take too much (overdose)

In case of overdose of Desud Plus, you must go or be taken immediately to an emergency centre or hospital for treatment.

Advise immediately your doctor or your pharmacist.

While you are using Desud Plus

Things you must do

Sublingual route is the only efficacious administration route for this product. Do not swallow, crush or chew the tablets.

Keep the tablet under your tongue until it dissolves. This may take 5-10 minutes. You must follow the dosage recommended by your doctor.

Things you must not do

Do not stop the treatment without consulting your doctor. Stopping treatment suddenly may cause withdrawal symptoms.

Desud Plus may cause drowsiness, particularly when taken together with alcohol or central nervous system depressants (such as tranquilisers, sedatives or hypnotics). If you feel tired or sleepy, do not drive a motor vehicle or operate machinery.

Do not use Desud Plus to treat any other conditions unless your doctor tells you to.

Do not give or recommend Desud Plus to anyone else, even if they have the same condition as you.

Things to be careful of

Due to the lack of data in adolescents (age 15≤18), Desud Plus should be used only with caution in this age group.

Care must be taken when using Desud Plus in combination with benzodiazepines and other depressants such as alcohol or opioids, as deaths have been reported due to respiratory depression resulting from this combination.

You must follow the prescribing information by your doctor; deaths have been reported because of failure to adhere strictly to prescribing information.

As buprenorphine is an opioid, pain as a symptom of a disease may be reduced. Remember to inform your doctor or pharmacist if you are taking Desud Plus.

If you are an athlete, be aware that this medicine may cause a positive reaction to 'anti-doping' tests.

Cases of acute hepatic injury (liver problems) have been reported in a context of misuse, especially by intravenous route and at a high dose. These injuries could be due to special conditions such as viral infections (chronic C hepatitis), alcohol abuse, anorexia, or medicines association (for example: antiretroviral nucleoside analogues, acetylsalicylic acid (aspirin), amiodarone, isoniazid, valproate). 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.

Studies in animals, as well as clinical experience, have demonstrated that buprenorphine may produce dependence but at a lower level than morphine.

This product can cause drowsiness which may be increased by alcohol or anti-anxiety medicines.

As with other opioids, caution is requested if you have head injury, increased intracranial pressure, hypotension, prostatic hypertrophy or urethral stenosis.

This product should be used with care if you have asthma or respiratory insufficiency, renal insufficiency, or hepatic insufficiency.

Patients with rare hereditary problems such as galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Side effects

Like all medicines, Desud Plus tablet can cause side effects, although not everybody gets them.

The most common side effects are constipation and symptoms commonly associated with drug withdrawal (i.e. insomnia (inability to sleep), headache, nausea and sweating).

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/rash. These may be signs of a life-threatening allergic reaction.
- Feeling drowsy and uncoordinated, have blurred vision, speech problems, 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 or itching with yellowing of skin or eyes. These may be symptoms of liver damage.
- seeing or hearing things that are not there (hallucinations).

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10): Insomnia (inability to sleep), constipation, nausea, sweating, headache, drug withdrawal syndrome.

Common (affects 1 to 10 users in 100): Weight loss, swelling (hands and feet), tiredness, drowsiness, anxiety, nervousness, tingling, depression, decreased sexual drive, increase in muscle tension, abnormal thinking, tearing disorder, blurred vision, flushing, increased blood pressure, migraines, runny nose, sore throat and painful swallowing, increased cough, upset stomach, diarrhoea, abnormal liver function, loss of appetite, flatulence, vomiting, 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 syndrome, feeling of general discomfort, accidental injury, faintness and dizziness, drop in blood pressure on changing position from sitting or lying down to standing.

Uncommon (affects 1 to 10 users in 1,000): Swollen glands (lymph nodes), agitation, tremor, abnormal dream, excessive muscle activity, depersonalization (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, palpitations, 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.

Rare (affects 1 to 10 users in 10,000): Slow or difficult breathing, liver injury with or without jaundice, hallucinations, swelling of face and throat or life threatening allergic reactions.

Not known (frequency cannot be estimated from the available data): Sudden withdrawal syndrome caused by taking Desud Plus too soon after use of illicit opioids, spontaneous abortion, drug withdrawal syndrome in newborn.

Misusing this medicine by injecting it can cause withdrawal symptoms,

infections, other skin reactions and potentially serious liver problems.

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.

After using Desud Plus

Storage

Store below 30°C, away from direct sunlight in a cool and dry place.

This product must be locked and kept safely away from children. Do not store it anywhere where children may get hold of it.

Do not use Desud Plus after the expiry date which is stated on the carton.

Disposal

If your doctor tells you to stop taking Desud Plus, or your tablets have passed their expiry date, ask your pharmacist or doctor what to do with any that are left over.

Do not simply throw the left over or expired products into the dustbin.

Product Description

What it looks like

The tablets are orange, hexagon, biconvex tablets, debossed with “LP” on one side and “24” on the other side for identification purpose.

Ingredients

Each Desud Plus 8 mg/2 mg sublingual tablet contains Buprenorphine 8.0mg and Naloxone 2.0mg.

The other ingredients are lactose monohydrate, povidone, Acesulfame potassium A.K.S., FD&C yellow No. 6, lemon flavor, citric acid anhydrous, Trisodium citrate dihydrate, corn starch, mannitol, and magnesium stearate.

MAL Number:

MAL 11095004AZ

Manufacturer

Lotus Pharmaceutical Co., Ltd.

No.30, Chenggong 1st Rd, Sinsing Village, Nantou City, Nantou County 540, Taiwan.

Product Registration Holder

Medicell Pharmaceutical (Malaysia) Sdn Bhd (898390-M)
Suite 16-03, Menara AmFIRST, 1, Jalan 19/3, 46300 Petaling Jaya, Selangor, Malaysia

Date of revision

8/02/2016