Package leaflet: Information for the user

LUPAXIS 25 mg Prolonged-release Tablets
LUPAXIS 50 mg Prolonged-release Tablets
LUPAXIS 100 mg Prolonged-release Tablets
LUPAXIS 150 mg Prolonged-release Tablets
LUPAXIS 200 mg Prolonged-release Tablets
LUPAXIS 250 mg Prolonged-release Tablets

tapentadol

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

What is in this leaflet

1. What LUPAXIS is and what it is used for

The full name of your medicine is 'LUPAXIS Prolonged-release Tablets'
It is referred to as 'LUPAXIS' in this leaflet.

LUPAXIS contains the active substance tapentadol. Tapentadol is a strong painkiller which belongs to the class of opioids. Tapentadol is used in adults for the treatment of:
- severe long-term pain that can only be adequately managed with an opioid painkiller.
- severe chronic pain in children above 6 years and adolescents that can only be adequately managed with an opioid painkiller.

2. What you need to know before you take LUPAXIS

Do not take LUPAXIS
- if you are **allergic** to tapentadol or any of the other ingredients of this medicine (listed in section 6)
- if you have **asthma** or if your breathing is dangerously slow or shallow (respiratory depression, hypercapnia)
- If you have paralysis of the gut
- if you have poisoning with alcohol, sleeping pills, pain relievers or medicines that affect mood and emotions (see 'Other medicines and LUPAXIS ')

Warnings and precautions
Talk to your doctor or pharmacist before taking LUPAXIS if you:

- have slow or **shallow breathing**
- suffer from **increased pressure** in the brain or are not fully conscious.
- have had a **head injury** or **brain tumours**
- suffer from **liver or kidney problems** (see 'How to take LUPAXIS ')
- suffer from a **pancreatic disease** including inflammation of the pancreas (pancreatitis) or disease of the bile duct (biliary tract disease)
- are taking medicines referred to as mixed **opioid agonist/antagonists** (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g. buprenorphine)
- have a tendency towards **epilepsy** or fits or if you are taking other medicines known to increase the risk of seizures because the risk of a fit may increase
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- are a smoker.
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

This medicine contains tapentadol which is an opioid medicine. Repeated use of opioid painkillers may result in the drug being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on LUPAXIS, it is important that you consult your doctor. Use (even at therapeutic doses) may lead to physical dependence, which may result in you suffering withdrawal effects and a recurrence of your problems if you suddenly stop taking this medicine treatment.

Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

LUPAXIS may lead to physical and psychological addiction. If you have a tendency to abuse medicines or if you are dependent on medicines, you should only take these tablets for short periods and under strict medical supervision.

Children and adolescents
Children and adolescents with obesity should be monitored closely and the recommended maximum dose should not be exceeded.

Do not give this medicine to children below the age of 6 years.

Sleep-related breathing disorders
LUPAXIS can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Other medicines and LUPAXIS
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor will tell you which medicines are safe to take with Tapentadol.

- The risk of side effects increases if you are taking medicines which may cause convulsions (fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take Tapentadolat the same time. Your doctor will tell you whether Tapentadol is suitable for you.
  Concomitantuse of LUPAXIS and sedative medicines such as benzodiazepines or related

medicines (certain sleeping pills or tranquillisers (e.g. barbiturates) or pain relievers such as opioids, morphine and codeine (also as cough medicine), antipsychotics, H1-antihistamines, alcohol, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma, and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe LUPAXIS together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor. The concomitant use of opioids and drugs used to treat epilepsy, nerve pain or anxiety (gabapentin and pregabalin) increases the risk of opioid overdose, respiratory depression and may be life-threatening. Please tell your doctor if you are taking gabapentin or pregabalin or any sedative medicines, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

- If you are taking a type of medicine that affects serotonin levels (e.g. certain medicines to treat depression), speak to your doctor before taking LUPAXIS as there have been cases of "serotonin syndrome". Serotonin syndrome is a rare, but life-threatening condition. The signs include involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension and body temperature above 38 oC. Your doctor can advise you on this
- Taking LUPAXIS together with other types of medicines referred to as mixed mu-opioid agonist/antagonists (e.g. pentazocine, nalbuphine) or partial mu-opioid agonists (e.g., buprenorphine) has not been studied. It is possible that LUPAXIS will not work as well if given together with one of these medicinal products. Tell your doctor in case you are currently treated with one of these medicinal products.
- Taking LUPAXIS together with strong inhibitors or inducers (e.g. rifampicin, phenobarbital or St John's Wort) of certain enzymes that are necessary to eliminate LUPAXIS from your body, may influence how well tapentadol works or may cause side effects, especially when this other medication is started or stopped. Please keep your doctor informed about all medicines you are taking.
- LUPAXIS should not be taken together with monoamine oxidase inhibitors (MAOIs - certain medicines for the treatment of depression). Tell your doctor if you are taking MAO inhibitors or have taken these during the last 14 days.

LUPAXIS with food, drink and alcohol
Do not drink alcohol whilst you are taking LUPAXIS , because some side effects such as drowsiness may be increased. . Food does not influence the effect of this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take this tablets:

- if you are pregnant, unless your doctor has instructed you to do so, , if used over prolonged periods during pregnancy, LUPAXIS may lead to withdrawal symptoms in the newborn baby, which might be life-threatening for the newborn if not recognized and treated by a doctor
- during childbirth, because it could lead to dangerously slow or shallow breathing (respiratory depression) in the newborn
- during breast-feeding, because tapentadol may be excreted in the breast milk

Driving and using machines
LUPAXIS may cause drowsiness, dizziness and blurred vision and may impair your reactions. This may especially happen when you start taking LUPAXIS , when your doctor changes your dosage or when you drink alcohol or take tranquilizers.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

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

3. How to take LUPAXIS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will change the dose and the interval between doses of LUPAXIS according to your pain level and your needs. Generally, the lowest pain-relieving dose should be taken.

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults
The usual dose is 1 tablet every 12 hours.
Total daily doses of Tapentadol greater than 500 mg tapentadol are not recommended.
Your doctor may prescribe a different, more appropriate dose or dosing schedule if this is necessary for you. If you feel that the effect of these tablets is too strong or weak, talk to your doctor or pharmacist.

Elderly patients
In elderly patients (above 65 years) usually no dose adjustment is necessary. However, the excretion of tapentadol may be delayed in some patients of this age group. If this applies to you, your doctor may recommend a different dosage regimen.

Patients with liver or kidney problems (insufficiency)
Patients with severe liver problems should not take these tablets. If you have moderate problems, your doctor will recommend a different dosage regimen. In case of mild liver problems, a dosage adjustment is not required.
Patients with severe kidney problems should not take these tablets. In case of mild or moderate kidney problems, a dosage adjustment is not required.

Use in children and adolescents
The dose of LUPAXIS for children and adolescents aged 6 years to less than 18 years is dependent on age and body weight.
The correct dose will be determined by your doctor. A total dose of 500 mg per day, i.e. 250 mg given every 12 hours should not be exceeded.
Children and adolescents with kidney or liver problems should not take these tablets.

LUPAXIS is not suitable for children below the age of 6 years.

How should you take LUPAXIS
LUPAXIS is for oral use.
Always swallow the tablets whole, with sufficient liquid. Don't chew it, break it or crush it – this could lead to overdosing, because the drug will be released into your body too quickly. You may take the tablets on an empty stomach or with meals.

The empty shell of the tablet may not be digested completely and thus be seen in stool. This should not worry you, since the medicine (active substance) of the tablet has already been absorbed in your body and what you see is just the empty shell.

How long should you take LUPAXIS
Do not take the tablets for longer than your doctor has told you.

If you take more LUPAXIS than you should
After taking very high doses, the following may be experienced

- pin-point pupils in the eyes,
- vomiting,
- drop in blood pressure,
- fast heart beat,
- collapse,
- disturbed consciousness or coma (deep unconsciousness),
- epileptic fits.
- dangerously slow or shallow breathing or stopping breathing may occur.

If this happens a doctor should be called immediately.

If you forget to take LUPAXIS
If you forget to take the tablets, your pain is likely to return. Do not take a double dose to make up for a forgotten dose; simply continue taking the tablets as before.

If you stop taking LUPAXIS
If you interrupt or stop treatment too soon, your pain is likely to return. If you wish to stop treatment, please tell your doctor first before stopping treatment.
Generally, there will be no after-effects when treatment is stopped. However, on uncommon occasions, people who have been taking the tablets for some time may feel unwell if they abruptly stop taking them.

Symptoms may be:

- restlessness, watery eyes, runny nose, yawning, sweating, chills, muscle pain and dilated pupils,
- irritability, anxiety, backache, joint pain, weakness, abdominal cramps, difficulty in sleeping, nausea, loss of appetite, vomiting, diarrhoea, and increases in blood pressure, breathing or heart rate.

If you experience any of these complaints after stopping treatment, please contact your doctor.

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Important side effects or symptoms to look out for and what to do if you are affected:
This medicine may cause allergic reactions. Symptoms may be wheeziness, difficulty breathing, swelling of the eyelids, face or lips, rash or itching which may cover your whole body

Another serious side effect is a condition where you breathe more slowly or weakly than expected (rare). It mostly occurs in elderly and weak patients.

If you are affected by these important side effects contact a doctor immediately.

Other side effects that may occur:

Very common (may affect more than 1 in 10 people)
- feeling sick (nausea),
- constipation.
- dizziness,
- drowsiness,
- headache.

Common (may affect up to 1 in 10 people)
- decreased appetite,
- anxiety,
- depressed mood,
- sleep problem,
- nervousness,
- restlessness,
- disturbance in attention,
- trembling,
- muscle twitches,
- flushing,
- shortness of breath,
- vomiting,
- diarrhoea,
- indigestion,
- itching,
- increased sweating,
- rash,
- feeling of weakness,
- fatigue,
- feeling of body temperature change,
- mucosal dryness,
- accumulation of water in the tissue (oedema).

Uncommon (may affect up to 1 in 100 people)
- allergic reaction to medicines (including swelling beneath the skin, hives, and in severe cases difficulty breathing, a fall in blood pressure, collapse, or shock),
- weight loss,
- disorientation,
- confusion,
- excitability (agitation),
- perception disturbances,
- abnormal dreams,
- euphoric mood,
- depressed level of consciousness,
- memory impairment,
- mental impairment,
- fainting,
- sedation,
- balance disorder,

- difficulty in speaking,
- numbness,
- abnormal sensations of the skin (e.g. tingling, prickling),
- abnormal vision,
- faster heartbeat,
- slower heartbeat,
- palpitations,
- decreased blood pressure,
- abdominal discomfort,
- hives,
- delay in passing urine,
- frequent urination,
- sexual dysfunction,
- drug withdrawal syndrome (see 'If you stop taking Tapentadol),
- feeling abnormal, irritability.

Rare (may affect up to 1 in 1,000 people)
- drug dependence,
- thinking abnormal,
- epileptic fits,
- near fainting,
- coordination abnormal,
- dangerously slow or shallow breathing (respiratory depression),
- impaired gastric emptying
- feeling drunk ,
- feeling of relaxation.

Not known (frequency cannot be estimated from the available data)
- delirium

In general, the likelihood of having suicidal thoughts and behaviour is increased in patients suffering from chronic pain. In addition, certain medicines for the treatment of depression (which have an impact on the neurotransmitter system in the brain) may increase this risk, especially at the beginning of treatment. Although tapentadol also affects neurotransmitters, data from human use of tapentadol do not provide evidence for an increased risk.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 affects you can help provide more information on the safety of this medicine.

5. How to store LUPAXIS

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.

This medicine does not require any special 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.

6. Contents of the pack and other information

What LUPAXIS contains

- The active substance is tapentadol.

  LUPAXIS 25 mg prolonged-release tablets
  Each prolonged-release tablet contains 38.28 mg of Tapentadol phosphate equivalent to 25 mg tapentadol

  LUPAXIS 50 mg prolonged-release tablets
  Each prolonged-release tablet contains 76.57 mg of Tapentadol phosphate equivalent to 50 mg tapentadol

  LUPAXIS 100 mg prolonged-release tablets
  Each prolonged-release tablet contains 153.13 mg of Tapentadol phosphate equivalent to 100 mg tapentadol

  LUPAXIS 150 mg prolonged-release tablets

  Each prolonged-release tablet contains 229.70mg of Tapentadol phosphate equivalent to 150 mg tapentadol

  LUPAXIS 200 mg prolonged-release tablets
  Each prolonged-release tablet contains 306.27 mg of Tapentadol phosphate equivalent to 200 mg tapentadol

  LUPAXIS 250 mg prolonged-release tablets
  Each prolonged-release tablet contains 382.84 mg of Tapentadol phosphate equivalent to 250 mg tapentadol

- The other ingredients are:
  Tablet core:
  microcrystalline cellulose
  hypromellose
  silica colloidal anhydrous
  magnesium stearate.

  Tablet coating:
  hypromellose
  glycerol
  talc
  microcrystalline cellulose
  titanium dioxide (E171)
  red iron oxide (25, 100, 150, 200 and 250 mg strengths only) (E172)
  yellow iron oxide (25, 100 and 200 mg strengths only) (E172)
  black iron oxide (25, 100, 150, 200 and 250 mg strengths only) (E172)

What LUPAXIS tablets looks like and contents of the pack

LUPAXIS 25 mg prolonged-release tablets are light brown , oblong, biconvex film-coated tablets (approximately 5.7 mm x 12,2 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.
LUPAXIS 50 mg prolonged-release tablets are white, oblong, biconvex film-coated tablets (approximately 6.2 mm x 13.2 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

LUPAXIS 100 mg prolonged-release tablets are light yellow , oblong, biconvex film-coated tablets (approximately 6.7 mm x 14.2 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.
LUPAXIS 150 mg prolonged-release tablets are light pink , oblong, biconvex film-coated tablet (approximately 7.2 mm x 15.2 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.
LUPAXIS 200 mg prolonged-release tablets are yellow, oblong, biconvex film-coated tablets (approximately 7.7 mm x 16.2 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.
LUPAXIS 250 mg prolonged-release tablets are reddish brown, oblong, biconvex film-coated tablets (approximately 8.7 mm x 18.2 mm) with score lines on both sides.
The score line is not intended for breaking the tablet.

LUPAXIS is available in pack sizes of:

LUPAXIS 25 mg prolonged-release tablets
20, 28, 30, 40, 50, 54, 56, 60 or 100 tablets in child resistant blisters.

LUPAXIS 50 mg,100 mg,150 mg,200 mg,250 mg Prolonged-release Tablets
20, 24, 28, 30, 50, 54, 56, 60 or 100 tablets in child resistant blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Dr. Reddy's Laboratories (UK) Ltd.410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, United Kingdom

Manufacturer
Develco Pharma GmbH
Grienmatt 27
79650 Schopfheim
Germany

Other formats of this leaflet
A service is available to listen to or request a copy of this leaflet in Braille, large print or audio.

Please call: +44 (0)1748 828873 (UK)

This leaflet was last revised in
11/2024