

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

(LEXOCAP) Paracetamol 325 mg, Ibuprofen 200 mg and Caffeine 30 mg capsule

Paracetamol, Ibuprofen and Caffeine

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 health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What LEXOCAP is and what it is used for
2. What you need to know before you take LEXOCAP
3. How to take LEXOCAP
4. Possible side effects
5. How to store LEXOCAP
6. Further information

1. WHAT LEXOCAP IS AND WHAT IT IS USED FOR

Each capsule contains the active ingredients PARACETAMOL 325 mg, IBUPROFEN 200 mg and CAFFEINE 30 mg. Other inactive ingredients (excipients) are Magnesium Stearate and Purified Talc. Paracetamol is an analgesic (pain killer) and antipyretic (helps to reduce body temperature when you have a fever) and caffeine acts to further help the effectiveness of Paracetamol. Ibuprofen belongs to a group of medicines called NSAID's (non steroidal anti-inflammatory drugs). It is an effective analgesic, anti-inflammatory and anti-pyretic.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LEXOCAP

Do not take LEXOCAP if you are sensitive to Paracetamol, ibuprofen or caffeine. Lexocap should not be taken if you suffer from or ever have suffered from stomach ulcers.

Cautions before you take LEXOCAP

Talk to your doctor or pharmacist before taking **LEXOCAP**

- If you have severe heart. Bowel, kidney or liver disease, including alcohol related liver disease.
- If you suffer from asthma
- If you are pregnant or breastfeeding
- If you are sensitive to aspirin
- If you suffer from systemic lupus erythematosus

If the answer to any of the above questions is YES, tell your doctor or pharmacist because LEXOCAP Capsules might not be suitable for you.

Interactions with other medicines

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. LEXOCAP can be affected by or have an effect on other medicines. Talk to your doctor or pharmacist before taking

LEXOCAP if you are taking any of the following medicines:

any other painkillers, anti-coagulants (blood thinners), anti-hypertensives (blood pressure tablets), or diuretics (water tablets), lithium, cyclosporin, steroid tablets or methotrexate, anti-depressants. Anti-epileptics, antivirals, baclofen, pentoxifyline, sibutramine, tacrolimus, quinoline antibiotics such as ciprofloxacin.

Taking LEXOCAP with food and drink

Lexocap should always be taken with food.

Pregnancy and breast-feeding

Lexocap should if possible be avoided during pregnancy especially in the last trimester. Only take Lexocap during pregnancy if it has been specifically prescribed by your doctor. Lexocap is not known to be harmful to the infant during breastfeeding, but only take this product during lactation on your doctor's recommendation.

3. HOW TO TAKE LEXOCAP

Always take LEXOCAP exactly as your health care provider has told you. You should check with your health care provider if you are not sure. Swallow the capsules whole with a drink of water. It is advisable to take LEXOCAP with food.

The usual doses are:

Adults and children 12 years and over:

Take 1 to 2 capsules every 6 hours as required. Lexocap should always be taken with food.

- Do not take more frequently than every 6 hours
- Do not take more than 6 capsules in 24 hours
- Do not give to children under 12 years of age

Avoid drinking too much coffee or tea when taking these capsules.

If symptoms persist then consult your doctor

If you take more LEXOCAP than you should

Immediate medical advice should be sought in the event of an overdose, even if you feel well because of the risk of delayed serious liver damage. Take your medicine pack with you so that people can see what you have taken.

If you forget to take LEXOCAP

If you forget a dose, take it as soon as you remember unless it is time for the next dose. Do not take two doses at the same time. Do not take a double dose to make up for a forgotten capsule.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Most people take these capsules without experiencing any problems. However, occasionally some people may get some adverse reactions, although this is rare. With ibuprofen the most frequent adverse effects are gastro-intestinal disturbances. Peptic ulceration and gastro-intestinal bleeding have been reported. Other side effects include headache, dizziness, nervousness, skin rash itching, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision and other ocular

reaction. Sensitivity reactions, abnormalities, or liver function tests, impairment of renal function and blood disorders have been observed. Acute, reversible renal failure has been reported. In view of the products inherent potential to cause oedema, heart failure may be precipitated in some compromised patients. In patients sensitive to Paracetamol, allergic reactions such as skin rashes may occur. Very rarely blood disorders have been reported although those effects may not have been caused by Paracetamol.

These effects should go away once you stop taking the medicine. If any side effects persist or worsen or you experience any other unusual side effects after taking this medicine, stop taking this medicine and inform your doctor or pharmacist at once.

Use in pregnancy and breast feeding

Lexocap should if possible be avoided during pregnancy especially in the last trimester. Only take Lexocap during pregnancy if it has been specifically prescribed by your doctor. Lexocap is not known to be harmful to the infant during breastfeeding, but only take this product during lactation on your doctor's recommendation.

5. HOW TO STORE LEXOCAP

Keep out of the reach and sight of children. Do not store above 25 °C. Store in the original carton and away from light. Do not use LEXOCAP after the expiry date which is stated on the carton after 'Exp'. LEXOCAP 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 LEXOCAP contains:

The active pharmaceutical ingredients of LEXOCAP are; Paracetamol, Ibuprofen and Caffeine. The other ingredients (excipients) are Magnesium Stearate and Purified Talc.

What LEXOCAP looks like and contents of the pack:

LEXOCAP is a hard gelatin capsule; Cap- light blue with LUEX logo, Body- dark blue with LEXOCAP printing. 10 capsules are packed in PVC/aluminum foil blisters and these blisters are packed in printed inner cartons along with an insert. 10 inner cartons are packed in outer cartons.

Manufacturer

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This leaflet was last approved on 05/2020.