

# ADEX 1,5 mg LP

## INN : Indapamide

**Please read carefully the integrality of this notice before taking this drug.**

- Keep this notice; you may need to read it again.
- If you have further questions, if you have any doubt, ask your doctor or pharmacist for more information.
- This drug was prescribed for you personally. Never give it to someone else, even in case of identical symptoms; this could be harmful for this person.
- If one of the undesirable effects worsens or if you experience an undesirable effect which is not mentioned in this notice, inform your doctor or your pharmacist.

**In this notice :**

1. What is ADEX 1,5 mg LP and in which case is it used ?
2. What is necessary to be known before taking ADEX 1,5 mg LP ?
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**1. WHAT IS ADEX 1,5 mg LP AND IN WHICH CASE IS IT USED ?**

This medicine is intended to reduce high blood pressure (hypertension). It is a prolonged-release film-coated tablet containing indapamide as active ingredient. Indapamide is a diuretic. Most diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced.

**2. WHAT IS NECESSARY TO BE KNOWN BEFORE TAKING ADEX 1,5 mg LP ?**

**Do not take ADEX 1,5 mg LP in the following cases :**

- If you are allergic to indapamide or any other sulfonamide or to any of the other ingredients of ADEX 1,5 mg LP;
- If you have severe kidney disease;
- If you have severe liver disease or suffer from a condition called hepatic encephalopathy (liver problems which affect the brain and central nervous system);
- If you have low potassium levels in your blood.

**Take special care with ADEX 1,5 mg LP**

- If you have liver problems,
- If you have diabetes,
- If you suffer from gout,
- If you have any heart rhythm problems or problems with your kidneys,
- If you need to have a test to check how well your parathyroid gland is working.

You should tell your doctor if you have had photosensitivity reactions.

Your doctor may give you blood tests to check for low sodium or potassium levels or high calcium levels.

If you think any of these situations may apply to you or you have any questions or doubts about taking your medicine, you should consult your doctor or pharmacist.

Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

In case of doubt, do not hesitate to ask your doctor's or your pharmacist's advice before receiving this drug.

**Taking other medicines**

You should not take ADEX 1,5 mg LP with lithium (used to treat depression) due to the risk of increased levels of lithium in the blood.

Make sure to tell your doctor if you are taking any of the following medicines, as special care may be required :

- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitalis);
- medicines used to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, antipsychotic drugs, neuroleptics);
- bepridil (used to treat angina pectoris, a condition causing chest pain);
- cisapride, diphepanil (used to treat gastric and intestinal problems);
- sparflloxacin, moxifloxacin (antibiotics used to treat infections);
- halofantrine (antiparasitic drug used to treat certain types of malaria);
- pentamidine (used to treat certain types of pneumonia);
- mizolastine (used to treat allergic reactions, such as hay fever);
- non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of acetylsalicylic acid;
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and heart failure);
- oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis;
- stimulant laxatives;
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis);
- potassium-sparing diuretics (amiloride, spironolactone, triamterene);
- metformin (to treat diabetes);
- iodinated contrast media (used for tests involving X-rays);
- calcium tablets or other calcium supplements;
- ciclosporin, tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases;
- tetracosactide (to treat Cohn's disease).

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

If you see a doctor, indicate that you follow a treatment with ADEX 1.5 mg LP. The latter is likely to affect other treatment or analysis results.

**Interactions with food and drinks**

Not applicable

**Interactions with herbal medicine or alternative therapy products**

Not applicable

**Pregnancy and breast-feeding**

The use of this medicine is not recommended during pregnancy. When a pregnancy is planned or confirmed, the switch to an alternative treatment should be initiated as soon as possible.

Please tell your doctor if you are pregnant or wish to become pregnant.

The active ingredient is excreted in milk. Breastfeeding is not advisable if you are taking this medicine.

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

**Sportsmen and sportswomen**

Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests

**Driving and using machines**

This medicine can cause side effects such as dizziness or tiredness due to lowering of the blood pressure (see section Possible side effects).

These side effects are more likely to occur after initiation of the treatment and after dose increases. If this occurs, you should refrain from driving and other activities requiring alertness. However, under good control, these side effects are unlikely to occur.

**Important information about some of the ingredients of ADEX 1,5 mg LP**

This medicine 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 ADEX 1,5 mg LP ?**

**Posology and Mode of administration :**

One tablet each day, preferably in the morning with or without food.

The tablet should be swallowed whole with water.

Do not crush or chew the tablet.

Treatment for high blood pressure is usually life-long.

**If you take more ADEX 1,5 mg LP than you should**

If you have taken too many tablets, contact your doctor or pharmacist immediately.

A very large dose of ADEX 1,5 mg LP could cause nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys.

**If you forget to take ADEX 1,5 mg LP :**

If you forget to take a dose of your medicine, take the next dose at the usual time.

Do not take a double dose to make up for the forgotten dose.

**If you stop taking ADEX 1,5 mg LP**

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping this medicinal product.

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

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, ADEX 1,5 mg LP can cause side effects, although not everybody gets them.

These side effects may include :

- Common (less than 1 patient in 10 but more than 1 in 100) : Low potassium in the blood, which may cause muscle weakness.
- Uncommon (less than 1 patient in 100 but more than 1 in 1000) : Vomiting, allergic reactions, mainly dermatological, such as skin rashes, purpura (red pinpoints on skin) in subjects with a predisposition to allergic and asthmatic reactions.
- Rare (less than 1 patient in 1000 but more than 1 in 10,000) :
  - \* Feeling of tiredness, dizziness, headache, pins and needles (paresthesia);
  - \* Nausea (feeling sick), constipation, dry mouth;
  - \* Increased risk of dehydration in the elderly and in patients suffering from heart failure.
- Very rare (less than 1 patient in 10,000) :
  - \* Heart rhythm irregularities (causing palpitations, feeling of the heart pounding), low blood pressure;
  - \* Kidney disease;
  - \* Pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function. In cases of liver failure, there is a possibility of getting hepatic encephalopathy (liver problems which affect the brain and central nervous system);
  - \* Changes in blood cells, such as thrombocytopenia (decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopenia (decrease of white blood cells which may cause unexplained fever, soreness of the throat or other flu-like symptoms - if this occurs, contact your doctor) and anaemia (decrease in red blood cells);
  - \* Angioedema and/or urticaria, severe skin manifestations. Angioedema is characterised by swelling of the skin around the eyes, lips, hands or feet. It may cause swelling of the throat, tongue or airways resulting in shortness of breath or difficulty in swallowing. If this occurs, contact your doctor immediately.
- If you suffer from systemic lupus erythematosus (a disorder of the immune system leading to inflammation and damage to the joints, tendons and organs with symptoms including skin rashes, tiredness, loss of appetite, weight gain and joint pain), this might get worse. Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.
- Changes may occur in your blood and your doctor may need to give you blood tests to check your condition. The following changes in your blood test results may occur :
  - Low potassium in the blood;
  - Low sodium in the blood that may lead to dehydration and low blood pressure;
  - Increase in uric acid, a substance which may cause or worsen gout (painful joint(s) especially in the feet);
  - Increase in blood glucose levels in diabetic patients;
  - Increase of calcium in blood.

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.

**5. HOW TO STORE ADEX 1,5 mg LP ?**

Keep out of the reach and sight of children.

Store away from humidity and at room temperature (15° - 25° C)

**6. FURTHER INFORMATION**

**a. What ADEX 1,5 mg LP contains**

	ADEX 1,5 mg LP
Active substance :	
Indapamide	
Excipients : Lactose, hydroxypropyl methylcellulose, magnesium stearate, colloidal silica, Opadry .....	s.q.f. one tablet
Active excipient : Lactose	

**b. What ADEX 1,5 mg LP looks like and contents of the pack**

ADEX 1,5 mg LP is a white, round (8 mm in diameter) prolonged-release film-coated tablet.

Tablets are available in blister of 30 tablets packed in a cardboard box.

**c. Marketing Authorization Holder and manufacturer**

Marketing Authorization Holder : Les Laboratoires MédiS – Route de Tunis Km 7 – BP 206 – 8000 Nabeul ; Tunisie.

Manufacturer : Les Laboratoires MédiS – Route de Tunis Km 7 – BP 206 – 8000 Nabeul ; Tunisie.

**d. Last approval date of this notice :**

Octobre 2011.

**e. Delivery conditions**

List II

**This is a drug**

- A drug is a product but it is different from the other products.
- A drug is a product which acts on your health and its non appropriate consumption can expose you to danger.
- Rigorously respect your doctor's prescription and the mode of administration he prescribed. Follow your pharmacist's advices.
- Your doctor and your pharmacist know drugs, their indications and contra-indications.
- Do not stop on your own initiative the treatment during the prescribed period
- Do not retake, do not increase doses without consulting your doctor.

**KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.**