PACKAGE INSERT

Lidaprim® oral suspension for children

Manufacturer
HAFSLUND NYCOMED PHARMA AG, Linz

Composition
5 ml (1 measuring spoon) contain
200 mg sulfametrole
40 mg trimethoprim
10 mg saccharin sodium

Properties and efficacy
LIDAPRIM® is used for the treatment of bacterial infectious diseases.

Indications
ENT infections and infections of the respiratory tract: inflammation of the tonsils, inflammation of the pharyngeal mucosa, inflammation of the ears, inflammation of the paranasal sinuses, inflammation of the lining of the larynx, acute and chronic bronchitis, bronchiectases (abnormal dilatation of bronchi), inflammation of the lungs.
Infections of the kidneys and of the urinary tract: acute and chronic inflammation of the kidneys and of the renal pelvis, inflammation of the urinary bladder, inflammation of the urethra.
Infections of the gastro-intestinal tract: inflammation of the biliary ducts and of the gallbladder, inflammation of the bowels, typhoid, paratyphoid; chronic Salmonella carriers.
Skin infections: purulent skin diseases, furuncles, abscesses, wound infections.

Mode of application and dosage
Unless otherwise prescribed by your doctor, strictly adhere to the dosage recommended.

Age	measuring spoons a day
6 weeks — 2 years	2 x ½
2 years — 3 years	2 x 1
3 years — 6 years	2 x 1½
6 years — 12 years	2 x 2

In cases of reduced renal function, the dosage has to be decreased according to the doctor's prescriptions.
The oral suspension should be taken after the meals in the morning and evening at intervals of about 12 hours.
LIDAPRIM® should be applied for at least 5 days. The treatment should be continued until the patient has been symptom-free for 2 days.

Contra-indications
The oral suspension must not be taken in cases of: intolerance of sulphonamides and trimethoprim, severe hepatic and renal damage, icterus, severe changes in blood picture.
Certain skin diseases which may also have occured earlier (Stevens-Johnson syndrome = erythema).
Drying of the skin, mucous membranes and internal organs may occur if the fluid supply is insufficient.
LIDAPRIM® should not be applied in neonates in the first six weeks of life and in premature babies.
LIDAPRIM® should also not be taken in the intervals during the treatment with certain medicines inhibiting the growth of malignant tumours.
Be cautious in cases of hepatic dysfunctions and renal insufficiency.

Pregnancy and lactation period:
If the drug is given to adults, please note that LIDAPRIM® must not be applied during pregnancy or lactation period.

Side effects
Occasionally nausea, vomiting, impairment of bile flow, changes in sensation of taste, changes in blood laboratory tests (increase of serum transaminases, bilirubin, BUN, serum creatinine) may occur.
In isolated cases, diarrhoea, lack of appetite, dryness of the mouth, pain and spasm in the stomach, headache, pain in a joint and allergies (e.g. itching eruption, fever, in rare cases Stevens-Johnson syndrome or Lyell's syndrome = extensive eruption of blisters with skin desquamation) and changes in blood picture (abnormal decrease of platelets or of white cells in the blood, change in red cells, lack of granulocytes caused by allergies, skin bleedings) may be observed.
The overgrowing of non-sensitive germs, especially of the causative organism of moniliasis, may bring about a superinfection.

Interactions
LIDAPRIM® may interact with several drugs.
Drugs for the treatment of increased acid content of the stomach (heartburn) may influence the uptake of LIDAPRIM® via the digestive tract.
Local anaesthetics (benzocaine, procaine, tetracaine) lower the efficacy of LIDAPRIM®.
The blood sugar reducing effect of certain drugs for the treatment of diabetes (sulphonyl ureas) is increased by LIDAPRIM®. Therefore, blood glucose checks are recommended.
The intake of certain drugs for the treatment of urinary tract infections (methenamine) increases the risk of formation of crystals in the urine.
LIDAPRIM® increases the unwanted effects of certain drugs (methotrexate) inhibiting the growth of malignant tumours.
The efficacy of certain anticoagulant drugs (anti-coagulants of the type of dicoumarol) is increased by LIDAPRIM®. Regular blood coagulation tests are necessary.
Various antirheumatic agents and analgesics (pyrazolone derivatives) may support the rarely occurring haematological changes.
LIDAPRIM® may increase the efficacy of certain drugs for the treatment of epilepsy (phenytoin).
Combinations of LIDAPRIM® with antibiotics of the penicillin group are not recommended because the drugs mutually cancel their efficacy.
Rifampicin may decrease the efficacy of LIDAPRIM®.
Certain drugs promoting the uric acid excretion may increase the efficacy of LIDAPRIM®.
In patients who take a dose of more than 25 mg pyrimethamine a week for the prophylaxis of malaria, a kind of anaemia (megaloblastic anaemia) may be observed.

Tolerance effects
No known tolerance effects.

Special warnings
If rash, intense weariness, sore throat or one of the above-mentioned side effects occur, the doctor must immediately be consulted.
Long-term therapy requires regular liver and renal function tests and haemograms.
During the treatment with LIDAPRIM®, sufficient fluid supply and urine excretion must be provided.
Be cautious in cases of hepatic and renal dysfunctions.
Keep a check on thyroid dysfunctions.
Shake before use!
Note the expiry date!
Keep out of the reach of children!

Package sizes
50, 100 ml (with measuring spoon)
Should you have any questions, consult health-care professional!

HAFSLUND NYCOMED PHARMA AG
Linz, Austria
Austria's Leading Manufacturer of Pharmaceuticals

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