

HIVUS-LR [LOPINAVIR AND RITONAVIR FILM COATED TABLETS USP]

Lopinavir USP / Ritonavir USP (100mg/25mg, 200mg/50mg)

What is in this leaflet

1. What HIVUS-LR Tablets is used for
2. How HIVUS-LR Tablets works
3. Before you use HIVUS-LR Tablets
4. How to use HIVUS-LR Tablets
5. While you are using it
6. Side effects
7. Storage and Disposal of HIVUS-LR Tablets
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What HIVUS-LR Tablets is used for

HIVUS-LR Tablets is used as a combination treatment with other antiretroviral agents for the treatment of HIV infection.

How HIVUS-LR Tablets works

HIVUS-LR Tablets prevents the formation of mature, infectious virus, resulting in the formation of immature, non-infectious virus instead.

Before you use HIVUS-LR Tablets

- When you must not use it

Do not take HIVUS-LR Tablets if you are hypersensitive to Lopinavir or Ritonavir or any other ingredients in the product.

Do not take HIVUS-LR Tablets with any of the following medicines:

- astemizole or terfenadine (commonly used to treat allergy symptoms – these medicines may be available without prescription);
- midazolam taken orally (taken by mouth), triazolam (used to relieve anxiety and/or trouble sleeping);
- pimozide (used to treat schizophrenia);
- quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder);
- lurasidone (used to treat depression);

- ranolazine (used to treat chronic chest pain [angina]);
- cisapride (used to relieve certain stomach problems);
- ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches);
- amiodarone, dronedarone (used to treat abnormal heart beat);
- lovastatin, simvastatin (used to lower blood cholesterol);
- lomitapide (used to lower blood cholesterol);
- alfuzosin (used in men to treat symptoms of an enlarged prostate (benign prostatic hyperplasia (BPH)));
- fusidic acid (used to treat skin infections caused by *Staphylococcus* bacteria such as impetigo and infected dermatitis). Fusidic acid used to treat long-term infections of the bones and joints may be taken under doctor's supervision
- colchicine (used to treat gout) if you have kidney and/or liver problems
- elbasvir/grazoprevir (used to treat chronic hepatitis C virus [HCV]);
- ombitasvir/paritaprevir/ritonavir with or without dasabuvir (used to treat chronic hepatitis C virus [HCV]);
- neratinib (used to treat breast cancer);
- avanafil or vardenafil (used to treat erectile dysfunction);
- sildenafil used to treat pulmonary arterial hypertension (high blood pressure in the pulmonary artery). Sildenafil used to treat erectile dysfunction may be taken under doctor's supervision
- products that contain St John's wort (*Hypericum perforatum*).

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking HIVUS-LR Tablets if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take HIVUS-LR Tablets if you are breast-feeding.

- Before you start to use it

Talk to your doctor, if you have any of the following:

- Diabetes Mellitus
- Pancreas problem
- Liver problem
- Haemophilia
- Lipid disorders

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor particularly if you are taking the following medicines:

- antibiotics (e.g. rifabutin, rifampicin, clarithromycin);
- anticancer medicines (e.g. abemaciclib, afatinib, apalutamide, ceritinib, encorafenib, ibritinib,
- venetoclax, most tyrosine kinases inhibitors such as dasatinib and nilotinib, also vincristine and vinblastine);
- anticoagulants (e.g. warfarin, rivaroxaban, vorapaxar);
- antidepressants (e.g. trazodone, bupropion);
- anti-epilepsy medicines (e.g. carbamazepine, phenytoin, phenobarbital, lamotrigine and valproate);
- antifungals (e.g. ketoconazole, itraconazole, voriconazole);
- anti-gout medicines (e.g. colchicine). You must not take HIVUS-LR with colchicine if you have kidney and/or liver problems
- anti-tuberculosis medicine (bedaquiline, delamanid);
- antiviral medicine used to treat chronic hepatitis C virus (HCV) infection in adults (e.g. glecaprevir/pibrentasvir, simeprevir and sofosbuvir/velpatasvir/voxilaprevir);

HIVUS -LR [LOPINAVIR AND RITONAVIR FILM COATED TABLETS USP]

Lopinavir / Ritonavir (100mg/25mg, 200mg/50mg)

- erectile dysfunction medicines (e.g. sildenafil and tadalafil);
- fusidic acid used to treat long-term infections of the bones and joints (e.g. osteomyelitis);
- heart medicines including: digoxin; calcium channel antagonists (e.g. felodipine, nifedipine, nicardipine); medicines used to correct heart rhythm (e.g. bepridil, systemic lidocaine, quinidine);
- HIV CCR5-antagonist (e.g. maraviroc);
- HIV-1 integrase inhibitor (e.g. raltegravir);
- levothyroxine (used to treat thyroid problems);
- medicines used to lower blood cholesterol (e.g. atorvastatin, lovastatin, rosuvastatin or simvastatin);
- medicines used to treat asthma and other lung-related problems such as chronic obstructive pulmonary disease (COPD) (e.g. salmeterol);
- medicines used to treat pulmonary arterial hypertension (high blood pressure in the pulmonary artery) (e.g. bosentan, riociguat, sildenafil, tadalafil);
- medicines affecting the immune system (e.g. cyclosporin, sirolimus (rapamycin), tacrolimus);
- medicines used for smoking cessation (e.g. bupropion);
- pain-relieving medicines (e.g. fentanyl);
- morphine-like medicines (e.g. methadone);
- non-nucleoside reverse transcriptase inhibitors (NNRTIs) (e.g. efavirenz, nevirapine);
- oral contraceptive or using a patch contraceptive to prevent pregnancy
- protease inhibitors (e.g. fosamprenavir, indinavir, ritonavir, saquinavir, tipranavir);
- sedatives (e.g. midazolam administered by injection);
- steroids (e.g. budesonide, dexamethasone, fluticasone propionate, ethinyl oestradiol, triamcinolone).

How to use HIVUS-LR Tablets

- How much to use

Your doctor will tell you how much and the frequency to take HIVUS-LR Tablets, based on your condition and other medicines you may be taking.

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

HIVUS-LR Tablets is taken orally and may be taken with or without food. The tablet should be swallowed whole and not chewed, broken or crushed.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking HIVUS-LR Tablets for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking HIVUS-LR Tablets.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give HIVUS-LR Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, HIVUS-LR Tablets can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Commonly reported adverse reactions to lopinavir/ritonavir included diarrhoea, nausea and vomiting.

Other identified adverse reactions of moderate or severe intensity includes:

Anemia, vertigo, ringing in the ear, visual impairment, diarrhoea, nausea, vomiting, upper and lower abdominal pain, constipation, dry mouth, fatigue, urticaria, swelling, upper and lower respiratory tract infection, skin infection, weight loss, appetite loss, weight gain, increased appetite, back pain, muscle weakness, headache, migraine, difficulty falling asleep, dizziness.

HIVUS -LR [LOPINAVIR AND RITONAVIR FILM COATED TABLETS USP]

Lopinavir / Ritonavir (100mg/25mg, 200mg/50mg)

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my (Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of HIVUS-LR Tablets

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C. Store in the original package. Keep out of reach and sight of children.

- Disposal

Medicines 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.

Product Description

- What it looks like

HIVUS - LR 100/25 [Lopinavir 100mg and Ritonavir 25mg Film Coated Tablets USP]

Light Yellow Film-Coated Capsule Shaped tablets debossed with 'D91' on one side and plain on the other side

HIVUS - LR 200/50 [Lopinavir 200mg and Ritonavir 50mg Film Coated Tablets USP]

Light Yellow Film-Coated Ovaloid tablets debossed with 'X' on one side and '28' on other side.

- Ingredients

- Active ingredients

HIVUS - LR 100/25
Lopinavir USP 100mg,
Ritonavir USP 25

HIVUS - LR 200/50
Lopinavir USP 200mg,
Ritonavir USP 50

- Inactive ingredients

Copovidone, Sorbitan monolaurate, Colloidal silicon dioxide, Poloxamer 188, Sodium stearyl fumarate, Hypromellose, Polyethylene glycol 400, Polysorbate 80, Titanium dioxide, Ferric oxide yellow.

- MAL number(s):

HIVUS - LR 100/25 [Lopinavir 100mg and Ritonavir 25mg Film Coated Tablets USP]

MAL*****

HIVUS - LR 200/50 [Lopinavir 200mg and Ritonavir 50mg Film Coated Tablets USP]

MAL*****

Manufacturer

Aurobindo Pharma Limited
Unit-III, Sy.No.313 and 314,
Block I, II, III, IV,
Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District,
Telangana State - 500090, India.

Product Registration Holder

Unimed Sdn Bhd,
No. 53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara, 52200,
Kuala Lumpur, Malaysia.

Serial Number:

NPRA (R2)22/040

Dosage Form

Film Coated Tablet

Packaging:

HIVUS-LR 100/25, 60 Film coated tablets packed in white HDPE container, with white Polypropylene child resistant closure with induction sealing with 1gram silica gel. HDPE container packed in carton along with package insert.

HIVUS-LR 200/50, 120 Film coated tablets packed in white HDPE container, with white Polypropylene child resistant closure with induction sealing with 1gram silica gel. HDPE container packed in carton along with package insert.

Date of revision

14/04/2023