

PATIENT LEAFLET: INFORMATION FOR THE USER

IMUNOVIR® 500mg TABLETS inosine acedoben dimepranol

Please read all of this leaflet carefully before you start taking this medicine. It contains important information.

- Keep this leaflet in a safe place because you may need to read it again.
- If you have any other questions, or if there is something you do not understand, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never give it to someone else. It may harm them. It may not be the right medicine for them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This leaflet contains the following information:

1. What Imunovir Tablets are and what they are used for
2. Before you take Imunovir Tablets
3. How to take Imunovir Tablets
4. Possible side effects
5. How to store Imunovir Tablets
6. Further information

1. What Imunovir Tablets are and what they are used for

Imunovir 500 mg Tablets help the body's immune system to fight viral diseases; it can also act directly on the invading virus.

Your doctor may prescribe Imunovir Tablets for the treatment of:

- Patients with a depressed immune system suffering from viral infections such as Chicken Pox (varicella), Herpes simplex virus infections such as cold sores and genital herpes (infections that occur on the sex organs) and Subacute Sclerosing Panencephalitis (SSPE), which is a very rare complication of measles
- Warts on the genitals in combination with other treatments such as podophyllin or carbon dioxide laser.

2. Before you take Imunovir Tablets

Do not take Imunovir Tablets if:

- You are allergic (hypersensitive) to inosine acedoben dimepranol (the active ingredient) or any of the other ingredients of Imunovir Tablets (see section 6.) Allergic reactions can include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- You currently suffer from gout or high levels of uric acid in your blood.

Take special care with Imunovir Tablets:

Talk to your doctor or pharmacist before taking Imunovir Tablets as these tablets might not be the right medicine for you if:

- You suffer from kidney problems
- Have had a history of gout, High levels of uric acid in the blood or stones in the kidney, bladder or urinary tract

There is a possibility that kidney stones or stones in the gall bladder may occur when patients receive long term treatment (more than 3 months) with Imunovir Tablets. If you are taking these tablets continuously for a long period of time your doctor will need to regularly check your liver and kidneys and also take regular blood and urine samples.

Using other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is particularly important if you are taking drugs that affect the immune system such as

Zidovudine (AZT – used to treat HIV). This is because Imunovir can affect the way these medicines work. Also, these medicines may affect the way Imunovir works.

Imunovir Tablets should be used with caution with xanthine oxidase inhibitors, uricosuric agents and diuretics (these are medicines that may be used to treat gout or control the amount of uric acid in your body).

Inform your doctor or pharmacist if you are taking or have recently taken these or any other medicines, even those not prescribed by a doctor.

Pregnancy and breast-feeding

You should not use Imunovir Tablets if you are pregnant. Please tell your doctor if you are pregnant. It is not known whether the active substance in this medicine passes into breast milk during use.

Please tell your doctor if you are breast-feeding.

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

Driving and using machines

Imunovir Tablets have no known effect on the ability to drive or use machines.

Important information about some of the ingredients of Imunovir Tablets

Imunovir Tablets contain wheat starch. This medicine is suitable for people with coeliac disease.

Patients with a wheat allergy (different from coeliac disease) should not take this medicine.

3 How to take Imunovir Tablets

Always take Imunovir Tablets exactly as your doctor has told you. You should check with your doctor if you are not sure. Read the label on your pack carefully.

Imunovir Tablets can be taken orally with or without food. If taking tablets is difficult for you, the tablets can be crushed and dissolved in a small amount of pleasant-tasting liquid. Drink all the liquid. Your doctor will decide the right dose for you, depending on your body weight and condition and advise you for how long to take your medication. It is important to take the tablets for the full length of treatment prescribed, even if your symptoms disappear before you are through taking the tablets.

The usual daily dose is:

For adults: Take 2 tablets, up to four (4) times each day during normal waking hours.

Use in children (Imunovir is for use in Children aged over 1 year only):

For children under 20 kgs: Take 1 tablet per 10kgs daily.

Children over 20 kgs: Take 2 tablets, up to four (4) times each day during normal waking hours

If you take more Imunovir Tablets than you should

Call the doctor for advice.

If you forget to take Imunovir Tablets

If you forget to take the tablets at the right time, take them as soon as you remember. Then go on as before. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

Like all medicines, Imunovir Tablets can cause side effects, although not everybody gets them.

In some people Imunovir may cause allergic reactions (hypersensitivity) which may mean you have difficulty in breathing or swallowing, swelling of the face, lips, throat or tongue, skin rashes, large or itchy wheals on the skin, attacks of sneezing, runny nose and itching eyes. If you experience any of these side effects, stop taking Imunovir and contact your doctor or pharmacist immediately.

The only very common side effect (affecting more than 1 in 10 people) is increased uric acid levels in the blood and urine which can cause gout and kidney stones. The level of uric acid in the blood returns to normal after the treatment is finished.

Common side effects (affecting less than 1 in 10 people) include:

- Nausea with or without vomiting, discomfort in the stomach
- Increased liver enzymes and blood urea nitrogen (a measure of the amount of nitrogen in the blood)
- Itching, skin rashes
- Headaches, vertigo, fatigue or malaise (feeling unwell)
- Painful joints

Uncommon side effects (affecting less than 1 in 100 people) include:

- Diarrhoea, constipation
- An increase in the amount of urine being passed
- Nervousness, drowsiness or insomnia

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not known (cannot be estimated from the available data)

- Allergic reactions which can include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- Dizziness
- Upper abdominal pain
- Flushing or redness of the skin
- Liver dysfunction, impairment of the bile flow (cholestasis),

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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Imunovir Tablets

- Keep out of reach and sight of children.
- Do not use the tablets after the last day of the month of the expiry date shown on the carton and the blister. Keep the blister in the outer carton in order to protect the tablets from light
- Do not store above 25°C
- 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. Only keep them if your doctor tells you to.

6. Further information

What Imunovir Tablets contain:

- The active substance is inosine acedoben dimepranol. Each tablet contains 500 mg inosine acedoben dimepranol.
- The other ingredients used to make the tablet are povidone, magnesium stearate, mannitol and wheat starch.

What Imunovir Tablets look like and contents of the pack:

Imunovir Tablets are white, oblong tablets with a score-line on one side and the letters 'DN' imprinted on the other. They are supplied in cardboard cartons containing 100 (5 x 20) tablets in blister packs sealed with aluminium foil.

THE MARKETING AUTHORISATION HOLDER IS:

Kora Corporation Ltd (trading as Kora Healthcare), Swords Business Park, Swords, Co. Dublin, Ireland

THE MANUFACTURER RESPONSIBLE FOR BATCH RELEASE IS:

Delpharm Dijon, 6 Boulevard de l'Europe, 21800 Quétigny, France

For any information about this medicinal product, please contact the Marketing Authorisation Holder - Kora Corporation Ltd (trading as Kora Healthcare). Tel + 353 -1- 8900406

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