

IMUNOVIR® 500mg TABLETS

inosine acedoben dimepranol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any other questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What are IMUNOVIR TABLETS and what are they used for
2. What you need to know before you take IMUNOVIR TABLETS
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1. What are IMUNOVIR TABLETS and what are they used for

Imunovir 500 mg tablets contains the active ingredient inosine acedoben dimepranol belonging to the group of antivirals. Imunovir tablets help the body's immune system to fight viral diseases; it can also act directly on the invading virus.

IMUNOVIR TABLETS may be used for three different conditions. Your doctor may prescribe IMUNOVIR TABLETS for the treatment of:

- Herpes Virus Infections caused by the herpes simplex virus that occur on the genitals (the sex organs), the skin and mucous membranes.
- Warts on the genitals. In treating these warts Imunovir 500mg tablets are used in combination with other treatment such as podophyllin or carbon dioxide laser.
- Subacute Sclerosing Panencephalitis (SSPE), which is a very rare complication of measles.

2. What you need to know before you take IMUNOVIR

Tablets

Do not take IMUNOVIR TABLETS :

- If you are allergic to inosine acedoben dimepranol (the active ingredient) or any of the other ingredients of this medicine (listed in section 6).
- You currently suffer from gout or high levels of uric acid in your blood.

Warnings and precautions

Talk to your doctor or pharmacist before taking IMUNOVIR TABLETS if:

- You suffer from kidney problems, gout, or high levels of uric acid in the blood.

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.

Other medicines and IMUNOVIR

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 TABLETS can affect the way these medicines work. Also, these medicines may affect the way IMUNOVIR TABLETS 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 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 IMUNOVIR TABLETS passes into breast milk during use. Please tell your doctor if you are breast-feeding.

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

Wheat starch in IMUNOVIR TABLETS contains only very low levels of gluten regarded as gluten free and is very unlikely to cause problems if you have coeliac disease. One tablet contains no more than 10.5 micrograms of gluten.

Patients with a wheat allergy (different from coeliac disease) should not take IMUNOVIR TABLETS

3. How to take IMUNOVIR TABLETS

Always take IMUNOVIR TABLETS exactly as your doctor has told you. 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.

The recommended dose is:

- *Herpes Simplex Infection*: Take 2 tablets four (4) times each day for 7-14 days.
- *Genital Warts*: Take 2 tablets, three (3) times each day for 14-28 days.
- *SSPE*: Your doctor will decide the right dose, depending on your body weight and advise you for how long to take your medication

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 TABLETS 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 TABLETS 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 been passed,
- nervousness, drowsiness or insomnia

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

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to Store IMUNOVIR TABLETS

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Unless your doctor tells you to, do not keep medicines that you no longer need.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other 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), 20 Harcourt Street, Dublin 2, D02 H364, Ireland THE

MANUFACTURER OF THE TABLETS IS

Delpharm Dijon, 6 Boulevard de l'Europe, 21800 Quetigny, 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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