

## 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 are IMUNOVIR TABLETS and what are they used for
2. Things to consider 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 are IMUNOVIR TABLETS and what are they used for

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. Things to consider 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 IMUNOVIR TABLETS (see Further Information section 6 for the list of ingredients).

**You should also ask yourself these questions before taking IMUNOVIR TABLETS.** If the answer to any of these questions is YES, tell your doctor or pharmacist because IMUNOVIR TABLETS might not be the right medicine for you.

- Do you suffer from kidney problems, gout, or high levels of uric acid in the blood? Please tell your doctor if you do.

### Using other medicines

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 after application. 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

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 IMUNOVIR TABLETS

### 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.

**The usual 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.

The only common side effect 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.

Less common side effects 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

Rare side effects include:

- diarrhoea, constipation,
- an increase in the amount of urine been 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.**

#### **Reporting of side effects**

If you get any side effects, talk to your doctor. 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](http://www.mhra.gov.uk/yellowcard).

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

#### **5. Storing IMUNOVIR TABLETS**

- 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 tablets in a secure place where children cannot get at or see them.
- Unless your doctor tells you to, do not keep medicines that you no longer need - give them back to your pharmacist for safe disposal.

#### **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 OF THE TABLETS 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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