

# Supraviran® 400

Tablets, for adults

Active substance: aciclovir



## COMPOSITION

1 tablet of SUPRAVIRAN 400 contains:

## ACTIVE COMPONENTS

400 mg aciclovir

## OTHER COMPONENTS

Sodium starch glycolate, sodium salt, copolyvidone, magnesium stearate, colloidal anhydrous silica, microcrystalline cellulose.

## DOSAGE FORM AND CONTENTS

Packs of 35 tablets.

**Prevents the growth of certain viruses.**

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## INDICATIONS

Shingles (herpes zoster).

Prevention of severe herpes simplex infections in adult patients whose immune system is extremely damaged at times of an increased risk of infection e.g. after organ transplantation.

## CONTRAINDICATIONS

### *When not to take Supraviran 400?*

If you are allergic to drugs containing aciclovir, you should not take SUPRAVIRAN 400.

During pregnancy your doctor will only prescribe SUPRAVIRAN 400 if absolutely necessary.

Since no information is available on the preventive use of SUPRAVIRAN 400 tablets in patients with impaired kidney function or considerably reduced urine production, the preparation should not be used in these conditions.

### *When must you consult your doctor before using SUPRAVIRAN?*

If you have problems with your kidney function or have had problems before, please inform your doctor.

### *What must be taken into account during pregnancy and breast-feeding?*

Pregnancy: if you are pregnant, your doctor will only prescribe SUPRAVIRAN 400 after assessing the benefit/risk ratio.

Breast-feeding: SUPRAVIRAN 400 passes into the breast milk; therefore breast-feeding should not be carried out during treatment with SUPRAVIRAN 400.

### *What about administration in children?*

In principle, children may be treated with aciclovir. However, the amount of the active substance in Supraviran 400 is intended for the treatment of adults, and therefore children should not be treated with Supraviran 400.

## PRECAUTIONS AND WARNINGS

### *What precautions must be taken into account?*

If you suffer from chronic kidney insufficiency or impaired kidney function, it may be necessary to reduce the dose of Supraviran 400.

### *What must be taken into account when driving, operating machines or working without a firm hold?*

Direct effects of aciclovir on reactions or road safety are not known. However, you must remember that in rare cases side-effects such as drowsiness, dizziness and hallucinations may occur, particularly if your kidney function is damaged.

## INTERACTIONS

### *Which other drugs may have an influence on the effect of SUPRAVIRAN 400?*

Probenecid - a drug given if the level of uric acid in the blood is too high - reduces the removal of aciclovir via the kidneys. This may prolong the effect of Supraviran 400.

Please remember that this may also apply, if you have recently taken any drugs.

### *Which foods or beverages should be avoided?*

Unfavourable effects of foods or beverages are not known.

## DOSAGE, MODE AND DURATION OF ADMINISTRATION

Unless otherwise prescribed by your doctor, the following dosage of Supraviran 400 applies. Please follow the instructions, otherwise Supraviran 400 will not be fully effective.

### *How much and how often should you take Supraviran 400?*

Adults with shingles receive two tablets (800 mg aciclovir) five times daily at intervals of four hours.

Patients whose immune system is very weakened or patients with impaired intestinal absorption: administration of the substance for intravenous infusion should be considered.

### *Prevention of herpes simplex infections in certain adults:*

In order to prevent severe herpes simplex infections in patients with a very weak immune system if they are exposed to an increased risk of infection (e.g. after organ transplantation), a single dose of 400 mg aciclovir (one tablet) may be taken four times daily at intervals of six hours.

In patients with impaired intestinal absorption administration of dry substance for intravenous infusion should be considered.

For patients with kidney insufficiency:

For patients with restricted kidney function a lower dose of aciclovir - as given below - may be sufficient.

| Indication | Creatinine clearance<br>(ml/min/1.73 m <sup>2</sup> ) | Serum creatinine (μmol/l/dl) |                       | Amount of a single dose   |
|------------|---|------------------------------|-----------------------|---|
|            |   | Women                        | Men                   |   |
| Shingles   | 25-10   | 280-550/<br>3.17-6.22        | 370-750/<br>4.18-8.48 | 800 mg aciclovir<br>(2 tablets)<br>three times daily<br>every 8 hours |
|            | <10   | >550/<br>>6.22               | >750/<br>>8.48        | 800 mg aciclovir<br>(2 tablets)<br>twice daily every 12 hours         |

#### **How and when should you take SUPRAVIRAN 400?**

SUPRAVIRAN 400 should, if possible, be taken after meals with large amounts of liquid.

Particularly in patients with restricted kidney function - especially elderly patients - care should be taken to see that sufficient liquid is drunk during treatment.

#### **How long should you take Supraviran 400?**

In herpes zoster infections (shingles) the duration of treatment is 5-7 days.

The duration of administration in the prevention of severe herpes simplex infections in patients with a very weak immune system depends on how weak their immune system is and how long there is a risk of infection. Your doctor will decide on the duration of treatment in your particular case.

Please keep to this time even if you already feel better.

#### **ERRORS IN ADMINISTRATION AND OVERDOSAGE**

##### **What should be done when too much Supraviran 400 has been taken (intentional or accidental overdose)?**

Only a part of the aciclovir is absorbed from the gut. Poisoning due to overdose after taking aciclovir by mouth is unlikely. No signs of poisoning occurred even when up to 5 g aciclovir had been taken in one. However, there are no reports of higher doses having been taken.

Inform your doctor if you have taken higher doses, and he will take any steps necessary.

##### **What should be done if you have not taken enough Supraviran 400 or have forgotten to take it?**

Please follow the doctor's instructions carefully.

If you forget to take the tablets once or several times, please consult your doctor.

If you wish to stop treatment on account of side-effects, please consult your doctor so that he can prescribe another preparation.

#### **SIDE-EFFECTS**

##### **Which side-effects may occur during treatment with Supraviran 400 and which steps may be taken?**

If you experience any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

After administration of SUPRAVIRAN 400 the following side-effects have occasionally been observed: rash, which disappeared when the drug was stopped, stomach troubles such as a feeling of sickness, vomiting, diarrhoea and stomach ache.

There have also been occasional neurological signs, such as dizziness, confusion, hallucinations and drowsiness. These side effects disappeared when the drug was stopped and mainly occurred in patients whose kidneys were not functioning properly or who were suffering from other diseases that may have played a part. Moreover, there have also been isolated reports of a feeling of estrangement which disappeared when the drug was stopped. Fits and psychoses, which disappeared later, have been reported when aciclovir was infused for complicated disease.

Certain laboratory tests on the liver, kidneys and blood showed some temporary rare changes (rises in bilirubin, liver enzymes, serum urea and creatinine and a slight fall in blood count).

Headache, listlessness, sleeplessness and tiredness have also been seen on rare occasions. There have also been rare cases of difficulties in breathing.

There have also been occasional reports of loss of hair, but it is not certain whether this was connected with treatment with Supraviran 400.

#### **NOTES AND DETAILS OF THE SHELF-LIFE OF THE DRUG**

The expiry date of this pack is printed on the top flap of the box and the blister pack. Do not use the pack after this date!

Supraviran 400 should not be stored at temperatures above 25 °C.

Please keep Supraviran 400 out of children's reach!

#### **DATE OF INFORMATION**

April 1995.