

PACKAGE LEAFLET: INFORMATION FOR THE USER

**Sulfadiazine 500mg Tablets**

**Sulfadiazine**

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is Sulfadiazine 500mg Tablets. In the rest of this leaflet it is called Sulfadiazine Tablets.

**In this leaflet:**

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

**1. What Sulfadiazine Tablets are and what they are used for**

The active ingredient in Sulfadiazine Tablets is sulfadiazine, which belongs to a group of medicines called sulphonamides. These are antibiotics that work by preventing the growth and multiplication of bacteria that cause infections.

Sulfadiazine Tablets are used in the treatment of a wide range of infections including food poisoning and meningitis.



**2. Before you take Sulfadiazine Tablets**

**Do not take Sulfadiazine Tablets if you:**

- are allergic to sulfadiazine or sulphonamides or any of the other ingredients contained in Sulfadiazine Tablets (see list under heading 'What Sulfadiazine Tablets contain' in section 6)
- have a kind of meningitis caused by meningococcus bacteria unless your doctor decides it is appropriate
- suffer from severe liver or kidney problems
- have jaundice (yellowing of the skin and/or whites of the eyes) or blood problems
- have porphyria (a rare condition affecting the production of haem, the red colouring in blood cells)
- are taking clozapine, a drug used to treat schizophrenia

If any of the above statements apply to you, you should not take Sulfadiazine Tablets.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of Sulfadiazine, appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk.

Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes).

These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

The highest risk for occurrence of serious skin reactions is within the first weeks of treatment.

If you have developed Stevens-Johnson

syndrome or toxic epidermal necrolysis with the use of sulfadiazine, you must not be re-started on sulfadiazine at any time.

If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him that you are taking this medicine.

**Sulfadiazine Tablets should not be given to babies under one month of age.**

**Speak to your doctor before taking Sulfadiazine Tablets if you:**

- are elderly
- have liver or kidney problems
- are predisposed to a lack of folic acid
- suffer from asthma or allergies
- have AIDS
- have a problem with your immune system called lupus erythematosus
- have a type of hereditary anaemia called glucose-6-phosphate dehydrogenase deficiency
- have jaundice (yellowing of the skin and/or whites of the eyes)

Your doctor may carry out blood tests or take urine samples if you are taking Sulfadiazine for a long time or if you are elderly.

Sulfadiazine treatment should be discontinued if a blood disorder develops. Tell the doctor or laboratory staff that you are taking sulfadiazine if you have to provide a urine sample.

If any of the above statements apply to you, you should speak to your doctor before taking Sulfadiazine Tablets.

**Taking other medicines**

Taking another medicine while you are taking Sulfadiazine Tablets can affect how it or the other medicine works.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, including those you may have bought yourself without a prescription.

Please check with your doctor if you are taking any of the following (or any other medication):

- **other antibiotics** such as pyrimethamine, methamine or trimethoprim
- **drugs used to thin the blood** e.g. warfarin
- **diuretics**, also called water tablets, which get rid of excess water in the body
- **anti-diabetic drugs** such as chlorpropamide or tolbutamide
- **drugs taken for epilepsy**, such as phenytoin
- **some drugs used to treat gout**, such as probenecid
- **some anti-inflammatory drugs**, such as aspirin
- **methotrexate**, a drug used for cancer
- **some general and local anaesthetics** such as procaine, prilocaine, benzocaine or tetracaine
- **drugs used to treat schizophrenia**, such as clozapine
- **oral contraceptives** – these may not work properly, so you should take additional contraceptive precautions during and for seven days after finishing a course of sulfadiazine
- **Potassium aminobenzoate**, used to treat a skin condition known as scleroderma
- **sunscreens** containing para amino benzoic acid (PABA)
- ciclosporin.

If you have had or are going to have an oral typhoid vaccination, Sulfadiazine should be avoided for 3 days before and after vaccination.

If you have any doubts about whether you should take this medicine then discuss the matter with your doctor before taking it.

**Taking Sulfadiazine Tablets with food and drink**

You should drink plenty of fluids (five to six pints per day) whilst taking Sulfadiazine Tablets, particularly in warm weather. Your doctor may give you something to make your urine more alkaline.

**Pregnancy and breast-feeding**

You should talk to your doctor before taking Sulfadiazine Tablets if you are pregnant or wish to become pregnant. Your doctor may allow you to take Sulfadiazine Tablets during the early stages of pregnancy. However, since sulfadiazine may affect your unborn child you should not take Sulfadiazine Tablets during late pregnancy.

Small amounts of sulphonamides pass into breast milk. You should talk to your doctor if you wish to breast-feed whilst taking Sulfadiazine Tablets since there is a risk of brain damage to your newborn child.

**Driving and operating machines**  
Sulfadiazine Tablets do not affect the ability to drive or operate machinery.

### 3. How to take Sulfadiazine Tablets

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely and also follow any special instructions or warnings which appear on the label which the pharmacist has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist.

Unless instructed differently, take your tablets with a glass of water.

#### Adults

The usual adult dose of Sulfadiazine Tablets is two to four grams (four to eight tablets) at the start of treatment, followed by four grams (eight tablets) daily in divided doses for up to seven days.

#### Children

The usual starting dose in children is 75mg per kg bodyweight followed by a maintenance dose of 150mg per kg bodyweight daily in divided doses, up to a maximum of six grams daily.

**Sulfadiazine Tablets should not be given to newborn babies.**

#### If you have kidney problems

Your dosage will be reduced if you have kidney problems.

#### Blood Tests

If you have to take Sulfadiazine Tablets for a long time, you should have regular blood tests.

#### If you take more Sulfadiazine Tablets than you should

If you accidentally take too many tablets contact your doctor, pharmacist or nearest hospital casualty department. Take this leaflet and any remaining tablets with you to show the doctor or pharmacist. Signs of an overdose include feeling sick and diarrhoea.

#### If you miss a dose of Sulfadiazine Tablets

If you forget to take a dose, take another as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a forgotten tablet.

#### Stopping Sulfadiazine Tablets

You should continue to take Sulfadiazine Tablets for as long as your doctor tells you to. Do not stop taking the medicine without talking to your doctor first.

### 4. Possible side effects

Like many medicines Sulfadiazine Tablets may cause side effects in some patients, although not everybody gets them.

Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported rarely (see section 2).

If you experience any of the following symptoms, **contact your doctor immediately as these may be signs of an allergic reaction:**

- difficulty breathing, swelling of your face or throat, or collapse
- rash, itching
- redness and blistering of the skin
- peeling of the skin
- sensitivity to light
- fever
- painful joints
- swelling of your lymph nodes
- feeling generally unwell
- problems with your kidneys
- problems with your liver which may become larger than usual
- jaundice (yellowing of your skin or whites of your eyes)
- inflammation of your heart muscle, blood vessels, pancreas or lungs
- blood disorders causing sore throat, mouth ulcers, infections or a tendency to bruise or bleed easily.

**Also contact your doctor immediately if you get:**

- severe diarrhoea
- lower back pain, and/or blood in your urine or if you seem to be passing less urine than usual. If any of these occur you should drink plenty of fluids.

#### Common side effects include:

- feeling sick

- being sick
- loss of appetite
- diarrhoea.

#### Other side effects include:

- blood problems causing bluish skin and lips
- low blood glucose
- underactive thyroid
- nervous system disorders such as symptoms of meningitis, problems with co-ordination, high pressure in your brain, headache, fatigue, dizziness, drowsiness, difficulty sleeping, fits or problems with your eyes
- depression
- cough or difficulty breathing
- swelling of the glands that produce saliva
- ringing in the ears
- fits, hallucinations.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below.

#### United Kingdom

Yellow Card Scheme

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

### 5. How to store Sulphadiazine Tablets

Keep this medicine out of the sight and reach of children.

Do not take this medicine if the expiry date on the label has passed. The expiry date refers to the last day of that month.

Sulfadiazine Tablets should not be taken if they show signs of deterioration such as discolouration.

Do not store above 25°C.

Store in the original container or package in order to protect from light and moisture. Do not transfer the tablets to another container.

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.

### 6. Further information

#### What Sulfadiazine Tablets contain

The active ingredient in Sulfadiazine Tablets is sulfadiazine.

Other ingredients are maize starch, pre-gelatinised starch, talc, magnesium stearate, microcrystalline cellulose and sodium starch glycollate.

#### What Sulfadiazine Tablets look like and contents of the pack

Sulfadiazine Tablets are plain, white tablets, curved on both faces and marked with CP on one face.

Sulfadiazine Tablets are available as 56 tablets in a plastic container packed in a carton.

#### Marketing Authorisation Holder:

Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

**Manufacturer:** CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

#### Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: **0800 198 5000 (UK Only)**

Please be ready to give the following information:

Product name	Reference number
Sulfadiazine 500mg Tablets	29831/0191

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was last revised in 09/2021.**

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