

DYFAZINE CREAM 1%

Silver Sulphadiazine (1% w/w)

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What Dyfazine Cream is used for

Indicated for the treatment and prevention of wound infection and prevention of sepsis (life threatening response to infection) in people with second and third degree burns.

How Dyfazine Cream works

Silver Sulphadiazine has broad antimicrobial activity against bacteria, yeast and fungi.

Before you use Dyfazine Cream

- When you must not use it

Do not use Dyfazine Cream in:

1. Premature and newborn babies (less than 2 months old).
2. Pregnancy

Pregnancy and lactation

It should be applied only in cases where the burnt area covers more than 20% of the total body surface or if the benefit of Dyfazine for the burnt individual is greater than the possible risk to the foetus. It is not known whether Dyfazine Cream is found in human milk, therefore caution should be exercised when used by nursing mothers.

Safety and effectiveness in children have not been established. Ask your doctor or pharmacists for advice before using Dyfazine Cream.

- Before you start to use it

Tell your doctor or pharmacist if you have:

1. Hypersensitivity to silver sulphadiazine or other sulfonamides.

2. Inborn deficiency of Glucose-6-Phosphate Dehydrogenase (G6PD) enzyme.
3. Liver or kidney impairment

- Taking other medicines

Tell your doctor if you are taking topical proteolytic enzymes and any other medicines, including that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Dyfazine Cream

- How much to use

Application

The burn wounds should be cleaned and the cream applied over all the affected areas to a depth of 3 – 5 mm. This application is best achieved with a sterile gloved hand and/or sterile spatula. Where necessary the cream should be reapplied to any area from which it has been removed by individual activity.

Follow all directions given to you by your doctor and pharmacists carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Dyfazine Cream for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

For topical application of sulphonamides, problems of overdose are unlikely to be encountered. Stop the medication and

consult the doctor immediately if any unusual serious reactions happened.

While you are using it

- Things you must do

Tell the doctor, dentist and pharmacist treating you that you are taking Dyfazine Cream.

- Things you must not do

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Dyfazine Cream to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

It should be used with caution in people with G6PD deficiencies which may cause the rupture or destruction of red blood cells after application of the cream to large areas of the body.

Side effects

Like all medicines, Dyfazine Cream can cause side effects, although not everybody gets them.

Side effects of Dyfazine Cream include:

- Sensitivity reactions in people with history of sulphonamide sensitivity.
- Temporary decrease in white blood cell's numbers has also occurred.
- Absorption of the Silver Sulphadiazine has also varies depending percentage of the body area and the extend of the tissue damage.
- Some reactions such as blood diseases, skin and allergic reactions, local reactions have been reported in people treated with silver sulphadiazine; the separation of the dead skin may be delayed and fungal invasion of the wound may occur, liver inflammation and cell death, Central Nervous System (CNS) reaction and kidney failure due to toxins and infections.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting

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Side Effects to Medicines (ConSERF)
or Vaccines (AEFI).

Storage and Disposal of Dyfazine Cream

- Storage

Keep out of reach of children
Store in dry place below 30°C
Protect from light
For external use only

- Disposal

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.

Product Description

- What it looks like

White colour with natural fragrance

- Ingredients

- Active ingredients
Silver Sulphadiazine

- Inactive ingredients

White Soft Paraffin, Liquid Paraffin,
Emulgate 1000 NI, Chlorocresol,
Purified Water & Glycerin

- MAL number

MAL19950334AZ

Manufacturer & Product registration holder

Dynapharm (M) Sdn. Bhd.
2497, Mk 1, Lorong Perusahaan Baru 5,
Kawasan Perusahaan Perai 3, 13600
Perai, Pulau Pinang, Malaysia.

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